UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

R.S.B., a minor, by and through his Parent and Next Friend, Stephanie Hammar, and STEPHANIE HAMMAR, Individually,

Plaintiffs,

v.

MERCK & CO., INC. and MERCK SHARP & DOHME CORP.,

Defendants.

CASE NO. 20-CV-01402-WCG

CIVIL LOCAL RULE 7(J) LIST OF AUTHORITIES FOR DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AS TO ALL CLAIMS ALLEGING INJURY FROM GENERIC MONTELUKAST

Pursuant to Civil L.R. 7(j), Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. provide the following list of unpublished cases cited in their Memorandum of Law in Support of Motion for Summary Judgment as to All Claims Alleging Injury from Generic Montelukast, and copies of the same:

1. *In re Zantac (Ranitidine) Prod. Liab. Litig.*, No. 9:20-md-02924, 2020 WL 7866660 (S.D. Fla. Dec. 31, 2020)

2. *Stirling v. Novartis Pharms. Corp.*, No. CV01-18-4880, 2019 WL 6456186 (Idaho Dist. Ct. Sept. 25, 2019)

3. *Trower v. Janssen Pharms., Inc.*, No. 1:16-cv-00135-RGA, 2019 WL 1571834 (D. Del. Apr. 11, 2019)

4. *Tarver v. Wyeth, Inc.*, No. 3:04-cv-02036, 2005 WL 4052382 (W.D. La. June 7, 2005)

5. *Evans v. Johnson & Johnson Co.*, No. 1:14-cv-01316, 2020 WL 616575 (D. Del. Feb. 10, 2020)

6. *Hopkins v. Janssen Pharms., Inc.*, No. 1:14-cv-01366-RGA, 2019 WL 1567840 (D. Del. Apr. 11, 2019)

7. *Neal v. Teva Pharms. USA, Inc.*, No. 09-cv-1027, 2010 WL 2640170 (W.D. Ark. July 1, 2010)

8. *Truddle v. Wyeth, LLC*, No. 2:11-CV-00207-GHD, 2015 WL 160696 (N.D. Miss. Jan. 12, 2015)

9. *Matherne v. Bayer Healthcare Pharms., Inc.*, No. 2:11-cv-02188, 2012 WL 12991011 (E.D. La. Nov. 2, 2012)

10. *Coundouris v. Wyeth*, No. ATL-L-0257-11, 2012 WL 2401776 (N.J. Super. June 26, 2012)

11. *Preston v. Janssen Pharms., Inc.*, No. 158570/17, 2018 WL 5017045 (N.Y. Sup. Ct. Oct. 12, 2018)

12. *Madden v. Teva Pharms. USA, Inc.*, No. 0087, 2012 WL 4757253 (Pa. Com. Pl. Oct. 1, 2012)

13. *In re Fluoroquinolone Products Liability Litigation*, No. 0:15-md-02642, 2021 WL 396819 (D. Minn. Feb. 4, 2021)

14. *Garner v. Johnson & Johnson, Janssen Research & Dev. LLC*, No. 1:16-cv-01494, 2017 WL 6945335 (C.D. Ill. Sept. 6, 2017)

15. *Cardinal v. Elsevier Inc.*, No. MICV201104442, 2014 WL 10937406 (Mass. Super. Aug. 11, 2014)

16. *Weese v. Pfizer, Inc.*, No. 153742/12, 2013 WL 5691993 (N.Y. Sup. Ct. Oct. 08, 2013)

17. *Dietrich v. Wyeth, Inc.*, No. 2009CA021586, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009)

18. *Westerlund v. Wyeth, Inc.*, No. MID-2174-05, 2008 WL 5592753 (N.J. Super. L. Oct. 20, 2008)

19. *Frase v. Ashland Chem. Co. Div. of Ashland, Inc.*, 2020 WL 1974190 (W.D. Wis. Apr. 24, 2020)

20. *In re: Mirapex Prods. Liab. Litig.*, No. 07-1836 (MJD/FLN), 2016 WL 4217758 (D. Minn. June 16, 2016)

21. *In re: Mirapex Prod. Liab. Litig. Gillette v. Boehringer Ingelheim Pharm., Inc.*, No. CV 15-3005 (MJD/FLN), 2016 WL 4203422 (D. Minn. Aug. 9, 2016)

22. *Short v. Eli Lilly and Co.*, No. 49D12-0601-CT-2187, 2009 WL 9867531 (Ind. Super. Mar. 25, 2009)

23. *Anselmo v. Sanofi-Aventis Inc. USA*, No. 10-cv-77, 2014 WL 8849464 (Kan. Dist. Ct. Oct. 13, 2014)

24. *Meade v. Parsley*, No. 2:09-cv-00388, 2009 WL 3806716 (S.D. W. Va. Nov. 13, 2009)

25. *Sheeks v. Am. Home Prods. Corp.*, No. 02CV337, 2004 WL 4056060 (Colo. Dist. Ct. Oct. 15, 2004)

26. *Rossi v. Hoffmann-LaRoche*, No. ATL-L690-05, 2007 WL 7632318 (N.J. Super. Jan. 03, 2007)

Dated: April 23, 2021

Respectfully submitted,

s/ Allen C. Schlinsog, Jr.

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United States District Court, S.D. Florida.

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
|
20-MD-2924
|
Signed 12/31/2020

Synopsis

Background: In multidistrict litigation (MDL), consumers of generic heartburn drug containing ranitidine filed complaints in 50 states, Puerto Rico, and District of Columbia against brand-name and generic drug manufacturers and others for state-law claims including negligence, negligent misrepresentation, and derivative claims, asserting innovator liability theory under laws of California and Massachusetts. Brand-name manufacturers moved to dismiss for failure to state a claim and lack of personal jurisdiction.

Holdings: The District Court, Robin L. Rosenberg, J., held that:

consumers failed to plead prima facie case of specific personal jurisdiction over each manufacturer in any state or territory;

under law of Alaska and other states, as predicted by the district court, brand-name manufacturers owed no duty to consumers of generic drug; and

under law of Arizona and other states, as predicted by the district court, lack of product identification precluded products liability claims.

Motion granted.

Procedural Posture(s): Motion to Dismiss for Lack of Personal Jurisdiction; Motion to Dismiss for Failure to State a Claim.

ORDER GRANTING BRAND-NAME MANUFACTURER DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' INNOVATOR-LIABILITY CLAIMS

ROBIN L. ROSENBERG, UNITED STATES DISTRICT JUDGE

***1** This matter is before the Court upon Brand-Name Manufacturer Defendants' ("Defendants") Rule 12 Motion to Dismiss Plaintiffs' Innovator-Liability Claims ("Motion to Dismiss"). DE 1585. The Court held a hearing on the Motion to Dismiss on December 14, 2020 (the "Hearing"). DE 2498. The Court has carefully considered the Motion to Dismiss, Plaintiffs' Opposition thereto [DE 1973], Defendants' Reply [DE 2132], the parties' supplemental briefing [DE 2307; DE 2335], the arguments that the parties made during the Hearing, and the record and is otherwise fully advised in the premises. For the reasons set forth below, the Motion to Dismiss is **GRANTED**.

I. Factual Background [1]

This case concerns the pharmaceutical product Zantac and its generic forms, which are widely sold as heartburn and gastric treatments. The molecule in question—ranitidine—is the active ingredient in both Zantac and its generic forms.

Zantac has been sold since the early 1980's, first by prescription and later as an over-the-counter medication. In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. MPIC ¶¶ 226, 231, 432. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 230. Zantac was a blockbuster—the first drug in history to reach $1 billion annually in sales. ¶ 231.

GSK entered into a joint venture with Warner-Lambert in 1993 to develop an over-the-counter ("OTC") form of Zantac. *Id.* ¶ 233. Beginning in 1995, the FDA approved the sale of various forms of OTC Zantac. *Id.* ¶¶ 233, 237. The joint venture between GSK and Warner-Lambert ended in 1998, with Warner-Lambert retaining control over the sale of OTC Zantac in the United States and GSK retaining control over the sale of prescription Zantac in the United States. *Id.* ¶ 234. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. *Id.* ¶ 235. The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. *Id.* ¶¶ 239-40, 242-44. When the patents on prescription and OTC Zantac expired, numerous generic drug manufacturers began to produce generic ranitidine products in prescription and OTC forms. *Id.* ¶¶ 249-51.

Scientific studies have demonstrated that ranitidine can transform into a cancer-causing molecule called N-nitrosodimethylamine ("NDMA"), which is part of a carcinogenic group of compounds called N-nitrosamines. *Id.* ¶¶ 253, 321, 324, 331. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 253, 264-72. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 254, 258. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶¶ 4, 263.

***2** Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a Citizen Petition on September 9, 2019, calling for the recall of all ranitidine products due to high levels of NDMA in the products. *Id.* ¶ 285. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 286. On November 1, the FDA announced that testing had revealed the presence of NDMA in ranitidine products. *Id.* ¶ 296. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Six months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 301.

II. Procedural Background

After the discovery that ranitidine products may contain NDMA, Plaintiffs across the country began initiating lawsuits related to their purchase and/or use of the products. On February 6, 2020, the United States Judicial Panel on Multidistrict Litigation created this multi-district litigation ("MDL") pursuant to 28 U.S.C. § 1407 for all pretrial purposes and ordered federal lawsuits for personal injury and economic damages from the purchase and/or use of ranitidine products to be transferred to the undersigned. DE 1. Since that time, hundreds of Plaintiffs have filed lawsuits in, or had their lawsuits transferred to, the United States District Court for the Southern District of Florida. In addition, this Court has created a Census Registry where thousands of claimants who have not filed lawsuits have registered their claims. *See* DE 547.

Plaintiffs filed three Master Complaints on June 22, 2020. DE 887, 888, 889. Plaintiffs contend that the ranitidine molecule is unstable, breaks down into NDMA, and has caused thousands of consumers of ranitidine products to develop various forms of cancer. MPIC ¶¶ 1, 6, 19. Plaintiffs allege that "a single pill of ranitidine can contain quantities of NDMA that are hundreds of times higher" than the FDA's allowable limit. *Id.* ¶ 4. Plaintiffs are pursuing federal claims and state claims under the laws

of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* CCCAC. The entities named as defendants are alleged to have designed, manufactured, tested, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine products. MPIC ¶¶ 20, 225.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order # 30, the Court set a case management schedule that is intended to prepare the MDL for the filing of *Daubert* motions on general causation and class certification motions in December 2021. DE 875; *see generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). In Pretrial Order # 36, the Court set a schedule for the filing and briefing of motions to dismiss under Federal Rule of Civil Procedure 12 directed to the Master Complaints. DE 1346. Defendants filed the instant Motion to Dismiss pursuant to that schedule.

III. The Master Personal Injury Complaint

For the purposes of this Order, the Court's references to "Plaintiffs" are to only those Plaintiffs who allegedly were injured solely by generic ranitidine products, not by brand-name ranitidine products. While there are fifteen counts asserted against Defendants in the MPIC, Plaintiffs acknowledged at the Hearing that the only substantive counts they are pursuing against Defendants are Counts VII and VIII. DE 2498 at 209; MPIC ¶¶ 542–73. Count VII is a claim for general negligence. MPIC ¶¶ 542–61. Plaintiffs allege that Defendants "breached their duty of reasonable care and failed to exercise ordinary care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products." *Id.* ¶ 551. Count VIII is a claim for negligent misrepresentation. *Id.* ¶¶ 561–73. Plaintiffs allege that Defendants "owed a duty to Plaintiffs to make accurate and truthful representations regarding ranitidine-containing products" and breached that duty. *Id.* ¶ 564. In this Order, the Court refers to Counts VII and VIII as Plaintiffs' "negligence-based claims." Additionally, Counts XIII-XV are derivative claims and include: loss of consortium, survival actions, and wrongful death. *Id.* ¶¶ 637–56.

***3** It is undisputed that all of Plaintiffs' claims against Defendants are based on a theory of liability that is currently only recognized under California and Massachusetts law. DE 1585 at 6; [2] DE 1973 at 15; *see also Rafferty v. Merck & Co.*, 479 Mass. 141, 92 N.E.3d 1205, 1219–20 (2018) (holding that, under Massachusetts law, brand-name manufacturers owe a duty to generic drug consumers not to act in reckless disregard of an unreasonable risk of death or grave bodily injury and allowing common law claims against brand-name manufacturers for recklessness but not for ordinary negligence); *T.H. v. Novartis Pharm. Corp.*, 4 Cal.5th 145, 226 Cal.Rptr.3d 336, 407 P.3d 18, 47–48 (2017) (holding that, under California law, brand-name manufacturers owe a duty to use ordinary care in warning about the safety risks of their drugs, regardless of whether the injured party consumed the brand or generic drug, and allowing claims of general negligence and negligent misrepresentation against brand-name manufacturers). This theory of liability has been referred to as "innovator liability." *See* Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand–Name and Generic Drug Manufacturers*, 60 Duke L.J. 1123, 1176 (2011). Under this theory of liability, the consumers of a generic drug product may hold a brand-name drug manufacturer liable for failing to warn of a defect in the product—a product that the brand-name drug manufacturer did not itself make, sell, or distribute. *See id.* The theory is based on a principle articulated in Section 311 of the Restatement (Second) of Torts, which provides in relevant part:

> One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results... to such third persons as the actor should expect to be put in peril by the action taken.

Restatement (Second) of Torts § 311(1)(b) (Am. Law Inst. 1965).

Here, Plaintiffs have pled that Defendants are liable for their alleged misrepresentations concerning the safety of ingesting brand-name ranitidine products which, according to Plaintiffs, created the market for generic ranitidine products, foreseeably led to the ingestion of generic ranitidine products, and, in turn, foreseeably led to generic consumers' injuries.

IV. Summary of the Parties' Arguments

Defendants filed the instant Motion to Dismiss seeking the dismissal of all claims asserted against them under Plaintiffs' theory of liability in all individual complaints, the MPIC, and Short Form Complaints adopting the MPIC. DE 1585 at 20. [3] Defendants' Motion to Dismiss has three primary arguments. First, claims brought in jurisdictions other than California and Massachusetts fail as a matter of law because those jurisdictions have yet to recognize Plaintiffs' theory of liability under their tort regimes. *Id.* at 13. Second, although California and Massachusetts recognize Plaintiffs' theory of liability under their respective tort regimes, Plaintiffs cannot assert their claims in the courts of those states because neither state has personal jurisdiction over Defendants. [4] *Id.* at 14. Lastly, Plaintiffs' claims fail even in those states in which Defendants are subject to general jurisdiction because those states are constrained by the Due Process Clause from applying the law of California or Massachusetts to Plaintiffs' claims. *Id.* at 17.

Plaintiffs argue that, in order to determine whether their theory of liability is viable under the laws of the jurisdictions that have not explicitly accepted or rejected it, the Court must make an *Erie* prediction by examining the law of each jurisdiction. DE 1973 at 15. These jurisdictions are likely to find Plaintiffs' theory of liability viable. *Id*. California and Massachusetts courts have specific personal jurisdiction over Defendants because of Defendants' alleged targeted marketing and labeling activities in those states. *Id.* at 24. And, because California and Massachusetts courts have specific personal jurisdiction over Defendants, California and Massachusetts courts also have legislative jurisdiction in other states and territories with personal jurisdiction over Defendants. *Id.* at 26.

***4** The Court ordered supplemental briefing from Plaintiffs and responsive supplemental briefing from Defendants on the issue of whether Plaintiffs' theory of liability may be viable under the laws of each jurisdiction that has yet to accept or reject the theory. DE 2228. [5] Thus, the parties provided briefing for the 35 remaining jurisdictions. DE 2307; DE 2335.

V. Summary of the Court's Rulings

The Court undertook the requisite *Erie* predictions, as set forth in Appendix A to this Order, and concludes that none of the 35 jurisdictions that the Court analyzed would recognize Plaintiffs' theory of liability under which Defendants may be held liable for injuries sustained by Plaintiffs' ingestion of a product that Defendants did not manufacture, sell, or distributed. *See Erie R. Co. v. Tompkins*, 304 U.S. 64, 78, 58 S.Ct. 817, 82 L.Ed. 1188 (1938). Additionally, the Court concludes that Plaintiffs failed to allege a prima facie case of specific personal jurisdiction as to any Defendant in California or Massachusetts and that California and Massachusetts do not have legislative jurisdiction within those states that have general personal jurisdiction over Defendants. Therefore, the Court grants the Motion to Dismiss. Plaintiffs' claims are dismissed without prejudice and with leave to amend to plead a prima facie case of personal jurisdiction in California and Massachusetts.

VI. Standards of Review

Defendants did not cite to any Federal Rule of Civil Procedure in their Motion to Dismiss. *See generally* DE 1585. However, Defendants informed the Court at the Hearing that they are moving to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction and Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. DE 2498 at 191.

A. Rule 12(b)(2)

A court may grant a motion to dismiss a pleading for lack of personal jurisdiction. Fed. R. Civ. P. 12(b)(2). At the pleading stage, the burden is on the plaintiff to establish a prima facie case of personal jurisdiction over the nonresident defendant. *See Consol. Dev. Corp. v. Sherritt, Inc.*, 216 F.3d 1286, 1291 (11th Cir. 2000). A prima facie case of personal jurisdiction is established if a plaintiff presents sufficient facts, entitled to the assumption of truth and viewed in the light most favorable to the plaintiff, to withstand a motion for directed verdict. *Id*. Non-specific statements providing "labels and conclusions" or "a formulaic recitation of the elements of [jurisdiction]" are not accepted as true and are insufficient to establish a prima facie case of jurisdiction. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007); *see, e.g.*, *Snow v. DirecTV, Inc.*, 450 F.3d 1314, 1318 (11th Cir. 2006) (holding that the plaintiff's "vague and conclusory allegations" presented in his complaint were insufficient to establish a prima facie case of personal jurisdiction over a defendant).

B. Rule 12(b)(6)

***5** A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). But the court need not accept legal conclusions couched as factual allegations. *Diverse Power, Inc. v. City of LaGrange, Ga.*, 934 F.3d 1270, 1273 (11th Cir. 2019). "Under Rule 12(b)(6), dismissal is proper when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action." *Allen v. USAA Cas. Ins. Co.*, 790 F.3d 1274, 1278 (11th Cir. 2015) (quotation marks omitted).

VII. Analysis

A. Plaintiffs' Theory of Liability Against Defendants

1. Arguments and Allegations

Defendants argue that this Court should align itself with the majority view that Plaintiffs' theory of liability—holding a brand-name manufacturer liable for injuries from a product it did not make, sell, or distribute—is invalid. DE 1585 at 13. Courts often reject the theory of liability because it ignores a fundamental principle of products liability law that requires a plaintiff to show that the product that caused injury was sold, manufactured, or distributed by the defendant. *Id.* at 10; *see In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.,* 856 F. Supp. 2d 904, 908 (E.D. Ky. 2012) ("[I]t is well-settled law that a 'threshold requirement of any products liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury.' ") (quoting *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011)), *aff'd*, 756 F.3d 917 (6th Cir. 2014); *In re Aredia & Zometa Prod. Liab. Litig.,* No. 3-06-MD-1760, 2010 WL 5136142, at *2 (M.D. Tenn. Dec. 7, 2010) (holding that traditional principles of products liability law require that the plaintiff prove the defendant supplied the product which caused the injury). As no Plaintiff was injured by a Defendant's product, the claims against them fail. DE 1585 at 10. Additionally, even if the fact that Plaintiffs were not injured by Defendants' products is ignored, Plaintiffs' negligence-based claims fail because courts have routinely held that a brand-name manufacturer owes no duty to generic consumers. *Id.* at 11.

Plaintiffs argue that Defendants' liability turns on whether they owe a duty to generic consumers. DE 1973 at 14. Defendants "intended for Plaintiffs and their physicians to reasonably and foreseeably rely on their misrepresentations about ranitidine-containing products in prescribing or recommending the drug to Plaintiffs, leading to their injuries." *Id.* at 16. Holding "brand-manufacturers liable for injuries caused by generic versions of their drugs is consistent with the long-standing rule that those who disseminate misinformation to the public are liable for physical harm to third parties resulting from foreseeable reliance on those misrepresentations." *Id.* at 17.

2. Law on *Erie* Prediction

A federal court sitting in diversity must apply state substantive law. *Erie*, 304 U.S. at 78, 58 S.Ct. 817. Where the highest state court has spoken on a topic, the federal court must follow its rule. *Molinos Valle Del Cibao, C. por A. v. Lama*, 633 F.3d 1330, 1348 (11th Cir. 2011). Where the highest state court has not spoken on the topic, the federal court must follow the decisions of intermediate appellate courts unless persuasive evidence demonstrates that the highest court would conclude otherwise. *Id.* If there is no explicit state law on an issue, "a federal court attempting to forecast state law must consider whatever might lend it insight, including 'relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand.' " *Guideone Elite Ins. Co. v. Old Cutler Presbyterian Church, Inc.*, 420 F.3d 1317, 1326 n.5 (11th Cir. 2005) (quoting *McKenna v. Ortho Pharm. Corp.,* 622 F.2d 657, 663 (3d Cir. 1980)). It is "generally presume[d] that [state] courts would adopt the majority view on a legal issue in the absence of indications to the contrary." *Bobo v. Tennessee Valley Auth.*, 855 F.3d 1294, 1304 (11th Cir. 2017) (citing *Wammock v. Celotex Corp.*, 835 F.2d 818, 820 (11th Cir. 1988)).

***6** However, when a federal court is called upon to recognize a cause of action under a state's laws that the state itself has yet to recognize, "considerations of comity and federalism counsel that [the federal court] proceed gingerly when venturing into uncharted waters of state substantive law." *Guarino v. Wyeth, LLC,* 719 F.3d 1245, 1251 (11th Cir. 2013) (declining to "manufacture" a law making brand-name manufacturers liable for the injuries of generic consumers "out of whole cloth," in part, because no Florida state court had adopted such law); *see also City of Miami v. Bank of Am. Corp.,* 800 F.3d 1262, 1289 (11th Cir. 2015) (declining "to invent a novel basis for unjust enrichment under Florida law" because the Florida Supreme Court had not yet ruled on whether such law existed and because of "the complete lack of supporting Florida caselaw").

3. Analysis and Conclusion

The Court has the task of making an *Erie* prediction as to whether the highest courts of 35 jurisdictions would recognize Plaintiffs' theory of liability. [6] In making its *Erie* predictions, the Court follows the *Erie* analysis steps set forth by the Eleventh Circuit. In addition to its own research, the Court relies upon the supplemental briefing provided by the parties. DE 2307; DE 2335. The Court's *Erie* predictions for the 35 jurisdictions are included in Appendix A.

As an initial matter, the Court recognizes that "the overwhelming national consensus—including the decisions of every [federal] court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product." *Guarino*, 719 F.3d at 1253 (finding no liability under Florida law of a brand-name manufacturer for injuries caused by ingestion of a generic drug); *see In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 941–54 (6th Cir. 2014) (holding that brand-name manufacturers cannot be held liable for damages caused by ingestion of generic drugs under negligent misrepresentation law of 22 states). [7] A small minority of federal and state courts have found that brand-name manufacturers owe a duty to generic consumers, reasoning that brand-name manufacturers know or should know that doctors foreseeably rely upon information relayed to them by brand-name manufacturers and foreseeably prescribe generic versions of the drug, which foreseeably causes injuries to generic consumers. [8]

***7** As the Sixth Circuit explained,

> There are two analytical avenues by which a state's highest court would determine whether Plaintiffs have stated viable [negligence and negligent misrepresentation] claims against Brand Manufacturers under applicable state law: (1) Plaintiffs' claims may be construed as strict "product liability" claims under the state's tort regime regardless of whether they are articulated as sounding in negligence [and negligent misrepresentation], or (2) even if they are seen as distinct and separate from product liability claims under

> a state's law, whether a duty exists between Brand Manufacturers and users of generic drugs that can give rise to liability.

In re Darvocet, 756 F.3d at 937. If the plaintiff's claims are construed as products liability claims, a threshold requirement is "product identification": for a plaintiff's claim to survive, the plaintiff must allege that she was injured by the defendant's product. *Id.* at 938.; *see also* Am. L. Prod. Liab. 3d § 5:1 (2020) ("[A] threshold requirement for a products liability action is that the plaintiff identify the manufacturer or supplier responsible for placing the injury-causing product into the stream of commerce; this is the traditional requirement that plaintiff establish causation.").

Although Plaintiffs argue that they are not pursing products liability claims against Defendants, as explained in Appendix A, the laws of some jurisdictions do not treat claims related to products that are pursued under a theory of negligence as distinct from products liability claims. Thus, if Plaintiffs' negligence-based claims are construed as products liability claims under state law, then for those claims to be viable under the laws of jurisdictions that require product identification, Plaintiffs must allege that the drugs that caused their injuries were made, sold, or distributed by Defendants. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (explaining that "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged"). For Plaintiffs' negligence-based claims viewed under state law as distinct from products liability claims to be viable, Plaintiffs must establish that Defendants owed Plaintiffs a duty sufficient to trigger liability.

The Court predicts that the highest courts of all 35 jurisdictions examined would hold that it is settled law that product identification must exist for a products liability claim to succeed. *See* Appendix A. The Court further predicts that the highest courts of Arizona, Arkansas, Colorado, Connecticut, Mississippi, North Carolina, and Oregon would hold that Plaintiffs' negligence-based claims are, in reality, products liability claims because all of Plaintiffs' claims stem from an injury caused by a product. The negligence-based claims are not distinct from products liability claims under the laws of these jurisdictions. Thus, because these states require product identification and Plaintiffs have not pled product identification, Plaintiffs' claims against Defendants of general negligence (Count VII) and negligent misrepresentation (Count VIII) fail under the laws of these jurisdictions.

***8** Lastly, the Court predicts that the highest courts of Alaska, Delaware, the District of Columbia, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Wisconsin, and Wyoming could hold that Plaintiffs' negligence-based claims are distinct from products liability claims. Consequently, the Court undertook further analysis to predict whether the highest courts of those jurisdictions would recognize a duty owed by Defendants to Plaintiffs that gives rise to liability. Based on the Court's review of each jurisdiction's analysis of when a duty is owed, the Court predicts that the highest courts of each of these jurisdictions would determine that Defendants do not owe a duty to Plaintiffs. This prediction comports with the principles of comity and federalism, which counsel federal courts to "proceed gingerly when venturing into uncharted waters of state substantive law." *Guarino*, 719 F.3d at 1251–53; *see also Douglas Asphalt Co. v. QORE, Inc.*, 657 F.3d 1146, 1154 (11th Cir. 2011) ("It is not the function of federal courts to expand state tort doctrine in novel directions absent state authority suggesting the propriety of doing so."); *City of Miami,* 800 F.3d at 1289 (declining "to invent a novel basis for unjust enrichment under Florida law" because the Florida Supreme Court had not yet ruled on whether such a claim existed and because of "the complete lack of supporting Florida caselaw"). Furthermore, this prediction is consistent with the majority view and is appropriate given the absence of any strong evidence that these jurisdictions would join the minority view. *See Bobo*, 855 F.3d at 1304 (holding that it is "generally presume[d] that [state] courts would adopt the majority view on a legal issue in the absence of indications to the contrary"). Plaintiffs' claims of general negligence (Count VII) and negligent misrepresentation (Count VIII) against Defendants fail under the laws of these jurisdictions.

In conclusion, the Court predicts that none of the highest courts of the 35 jurisdictions would recognize Plaintiffs' theory of liability. Thus, Counts VII and VIII of the MPIC by Plaintiffs against Defendants fail under the laws of the 35 jurisdictions for

failure to state a claim. And because Plaintiffs' substantive claims fail, so do their derivative claims, Counts XIII, XIV, and XV. *See In re Darvocet*, 756 F.3d at 936 (affirming a district court's dismissal of "derivative claims for wrongful death, survivorship, unjust enrichment, loss of consortium, and punitive damages" when the district court had dismissed all "underlying claims" because the derivative claims "stand or fall with the underlying claims on which they rest").

B. Personal Jurisdiction

1. Arguments and Allegations

Defendants argue that Plaintiffs have failed to establish specific personal jurisdiction in any state but focus their arguments on California and Massachusetts as the only two states that have explicitly recognized Plaintiffs' theory of liability. DE 1585 at 15. As to California and Massachusetts, personal jurisdiction over Defendants exists if Plaintiffs' claims " 'arise out of or relate to' actions" that Defendants took or directed to those states. DE 2132 at 10–11 (quoting *Bristol-Myers Squibb Co. v. Superior Ct. of Cal., S.F. Cty.*, —— U.S. ——, 137 S. Ct. 1773, 1780, 198 L.Ed.2d 395 (2017)). Further, "there must be an affiliation between the forum and the underlying controversy, principally, an activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation." DE 1585 at 15 (quoting *Bristol–Myers Squibb Co.*, 137 S. Ct. at 1780). The "controversy" in this case concerns the content of the label for generic ranitidine products and, thus, "the only conduct by the Brand-Name Manufacturers relevant to the innovator-liability claims" is "the labeling decisions," which "did not take place in California and Massachusetts." *Id.* at 16. Additionally, it makes no difference whether Defendants marketed their brand-name ranitidine products in California or Massachusetts because, to establish personal jurisdiction, Plaintiffs would have to allege "that such marketing of [brand-name ranitidine products] somehow caused them to take generic ranitidine" or "that the Brand-Name Manufacturers should have foreseen that their marketing of [brand-name ranitidine products] in California or Massachusetts would expose them to product-liability suits based on generic ranitidine." *Id.* at 12–13. Plaintiffs have not made either allegation, nor could they plausibly make such allegations. *Id.*

Plaintiffs argue that the jurisdictional allegations in the MPIC are "enough" to show personal jurisdiction over Defendants in California and Massachusetts. DE 1973 at 24. Specifically, Plaintiffs allege in the MPIC "labeling and marketing efforts within the states of California and Massachusetts (and elsewhere), which is where the [D]efendants 'targeted the consumer market.' " *Id.* (citing MPIC ¶ 221). Defendants' labeling and marketing efforts within California and Massachusetts "created the market for generic ranitidine and are thus 'affiliated' with the generic prescription and over-the-counter purchases that led to Plaintiffs' injuries." *Id.* at 25. "At the very least, Plaintiffs must be allowed to seek jurisdictional discovery into Defendants' labeling, sales, and advertising practices to disprove their denials of any connection to" California and Massachusetts. *Id.* at 26.

2. Law on Personal Jurisdiction

***9** There are two types of personal jurisdiction: general and specific. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919, 131 S.Ct. 2846, 180 L.Ed.2d 796 (2011). "A court may assert general jurisdiction over foreign (sister-state or foreign-country) corporations to hear any and all claims against them when their affiliations with the State are so 'continuous and systematic' as to render them essentially at home in the forum State." *Id.* (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316, 66 S.Ct. 154, 90 L.Ed. 95 (1945)). Absent exceptional circumstances, general personal jurisdiction over a corporation exists only in its place of incorporation and principal place of business. *See Daimler AG v. Bauman*, 571 U.S. 117, 138–39 & n.19, 134 S.Ct. 746, 187 L.Ed.2d 624 (2014).

Specific personal jurisdiction over a defendant is established when a plaintiff's claims arise out of or relate to the defendant's contacts with the forum, the defendant purposefully availed itself of the privilege of conducting activities in the forum, and the exercise of personal jurisdiction comports with traditional notions of fair play and substantial justice. *Louis Vuitton Malletier, S.A. v. Mosseri*, 736 F.3d 1339, 1355 (11th Cir. 2013) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 105 S.Ct. 2174, 85 L.Ed.2d 528 (1985)). Importantly, "a tort 'arise[s] out of or relate[s] to' the defendant's activity in a state only if the activity is a 'but-for' cause of the tort." *Waite v. Union Carbide Corp.*, 901 F.3d 1307, 1314 (11th Cir. 2018) (quoting *Oldfield v. Pueblo De Bahia Lora, S.A.*, 558 F.3d 1210, 1223 (11th Cir. 2009)).

> Whether specific or general, the exercise of personal jurisdiction over a defendant must comport with due process. The touchstone of this analysis is whether the defendant has certain minimum contacts with [the state] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.

Id. at 1312 (quoting *Int'l Shoe Co.*, 326 U.S. at 316, 66 S.Ct. 154). Traditional notions of fair play and substantial justice are not offended if "the defendant could reasonably foresee that it would cause harm within the forum and thereby had fair warning that it could be subject to suit ... based on the harm caused." *Oldfield*, 558 F.3d at 1223.

The minimum contacts analysis examines "the relationship among the defendant, the forum, and the litigation." *Walden v. Fiore*, 571 U.S. 277, 284, 134 S.Ct. 1115, 188 L.Ed.2d 12 (2014) (quotation marks omitted). "[The] unilateral activity of another party or a third person is not an appropriate consideration when determining whether a defendant has sufficient contacts with a forum State to justify an assertion of jurisdiction." *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 417, 104 S.Ct. 1868, 80 L.Ed.2d 404 (1984).

The burden is on the plaintiff to establish a prima facie case of personal jurisdiction over the non-resident defendant. *See Consol. Dev. Corp.*, 216 F.3d at 1291. A prima facie case of personal jurisdiction is established if a plaintiff presents sufficient facts, entitled to the assumption of truth and viewed in the light most favorable to the plaintiff, to withstand a motion for directed verdict. *Id*. Non-specific statements providing "labels and conclusions" or "a formulaic recitation of the elements of [jurisdiction]" are not accepted as true and are insufficient to establish a prima facie case of jurisdiction. *Bell Atl. Corp.*, 550 U.S. at 555, 127 S.Ct. 1955; *see, e.g.*, *Snow*, 450 F.3d at 1318 (holding that the plaintiff's "vague and conclusory allegations" presented in his complaint were insufficient to establish a prima facie case of personal jurisdiction over a defendant); *In re Takata Airbag Prods. Liab. Litig.*, 396 F. Supp. 3d 1101, 1148–49 (S.D. Fla. 2019) (concluding that plaintiffs failed to establish a prima facie case of personal jurisdiction over foreign defendants where the "generalized allegations [were] devoid of specificity, and thereby fail[ed] to establish that the Foreign Defendants 'purposefully availed' themselves of the privileges of conducting activity" in the states at issue).

3. Analysis and Conclusion

***10** Plaintiffs allege in the MPIC the states in which Defendants are incorporated and have their principal places of business and thus are subject to general personal jurisdiction. MPIC ¶¶ 21–36. The Court accepts these allegations as true at this stage in the litigation. *See Consol. Dev. Corp.*, 216 F.3d at 1291. At the Hearing, Plaintiffs acknowledged that each Defendant is subject to general personal jurisdiction only in the states in which it is incorporated and has its principal places of business. DE 2498 at 210; *see* MPIC ¶¶ 21–36.

Yet, Plaintiffs allege that all of the defendants in the MPIC are subject to specific personal jurisdiction in all U.S. states and territories. Specifically, Plaintiffs allege that:

> 220. Defendants have significant contacts with the federal judicial district identified in each Plaintiff's [Short Form Complaint] such that they are subject to the personal jurisdiction of the courts in each of those districts.
>
> 221. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products within the judicial district listed in the [Short Form Complaints] and targeted the consumer market within those districts.
>
> 222. At all times alleged herein, Defendants were authorized to conduct or engage in business within each of the States and Territories of the United States and supplied ranitidine-containing products within each of the States and Territories of the

> United States. Defendants received financial benefit and profits as a result of designing, manufacturing, testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling ranitidine-containing products within each of the States and Territories of the United States.
>
> 223. Defendants each have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their ranitidine-containing products in each of the States and Territories of the United States.

MPIC ¶¶ 220–23.

These allegations, however, do not establish a prima facie case of personal jurisdiction over Defendants in any identifiable state or territory. The allegations do not plead facts with sufficient specificity and are not tailored to any of the dozens of defendants named in the MPIC, nor are the allegations tailored to any particular state or territory. *See, e.g.*, *Snow*, 450 F.3d at 1318; *In re Takata*, 396 F. Supp. 3d at 1148–49.

Plaintiffs fail to allege specific, non-conclusory facts demonstrating that any of Defendants' actions, including marketing and labeling decisions, took place in any state or territory, including California or Massachusetts, the only two states that recognize Plaintiffs' theory of liability. To establish specific personal jurisdiction based on Defendants' activities in a particular state, Plaintiffs must allege that those activities were the "but-for" cause of Plaintiffs' ingestion of generic ranitidine products and injuries. *See Waite*, 901 F.3d at 1314 (holding that a tort arises out of or relates to a defendant's activity only if the activity is a but-for cause of the tort). Plaintiffs have failed to do so. Additionally, Plaintiffs must allege that Defendants should have foreseen that their activities regarding their brand-name ranitidine products in that state could expose them to liability for injuries sustained from the ingestion of generic ranitidine products. *See Oldfield*, 558 F.3d at 1223. Again, Plaintiffs have failed to do so.

***11** In conclusion, Plaintiffs have sufficiently alleged general personal jurisdiction for each Defendant only in the states in which the Defendant is at home, that is, the states in which it is incorporated and has its principal place of business. Plaintiffs have failed to allege a prima facie case of specific personal jurisdiction for Defendants in any U.S. state or territory. Accordingly, Counts VII, VIII, XIII, XIV, and XV of the MPIC by Plaintiffs against Defendants outside of Defendants' home states are dismissed without prejudice. [9]

C. Legislative Jurisdiction

1. Arguments and Allegations

Defendants' final argument is that, "[f]or the same reasons that Plaintiffs cannot establish specific jurisdiction over Defendants in California or Massachusetts courts, California or Massachusetts law cannot be extended to apply to claims brought in Defendants' home states where the courts have general jurisdiction." DE 1585 at 17. Plaintiffs respond that, "[i]f Defendants' *home states* would apply foreign law, that cannot be unconstitutional. For a Defendant's home state has the constitutional freedom—and territorial sovereignty—to borrow the rule of decision from any place it wishes." DE 1973 at 27.

2. Law on Legislative Jurisdiction

Legislative jurisdiction is a type of jurisdiction "relevant to determining the extraterritorial reach of a statute." *Hartford Fire Ins. Co. v. California*, 509 U.S. 764, 813, 113 S.Ct. 2891, 125 L.Ed.2d 612 (1993) (Scalia, J., dissenting) (explaining that legislative jurisdiction refers to "the authority of a state to make its laws applicable to persons or activities" beyond its borders). A state's legislative jurisdiction is limited by the Due Process Clause. *See Gerling Glob. Reinsurance Corp. of Am. v. Gallagher*, 267 F.3d 1228, 1236–37 (11th Cir. 2001). Courts "inquire not only into the contacts between the regulated *party* and the state, but also into the contacts between the regulated *subject matter* and the state." *Id.* at 1236 (emphasis in original). "There must be at least some minimal contact between a State and the regulated subject before it can, consistently with the requirements of due process, exercise legislative jurisdiction." *Hellenic Lines Ltd. v. Rhoditis*, 398 U.S. 306, 314 n.2, 90 S.Ct. 1731, 26 L.Ed.2d 252 (1970)

(Harlan, J., dissenting). To determine whether a state has legislative jurisdiction, a court must look to personal jurisdiction *and* choice-of-law analyses. *Gerling Glob.*, 267 F.3d at 1235.

Typically, a choice-of-law analysis will resolve any questions about whether a foreign state possesses legislative jurisdiction. This is so for two reasons. First, if a choice-of-law analysis results in the application of the forum's state law in lieu of a foreign state's law, the question of whether a foreign state possessed legislative jurisdiction becomes moot. Second, if a choice-of-law analysis results in the application of the law of a foreign state, such an analysis necessarily requires a consideration of fairness and due process—the precise question that must be considered in a due process challenge to legislative jurisdiction; a choice-of-law analysis requires "that [a] State must have a significant contact or significant aggregation of contracts, creating state interests, such that its choice of law is neither arbitrary nor fundamentally unfair." *Am. Charities for Reasonable Fundraising Reg., Inc. v. Pinellas Cnty.*, 221 F.3d 1211, 1216 (11th Cir. 2000) (citing *Allstate Ins. Co. v. Hague*, 449 U.S. 302, 101 S.Ct. 633, 66 L.Ed.2d 521 (1981)).

3. Analysis and Conclusion

***12** As the Court must conduct both a personal jurisdictional analysis and a choice-of-law analysis to consider legislative jurisdiction, the Court turns first to personal jurisdiction. Plaintiffs concede that "the same personal jurisdiction analyses apply to Defendants' due process arguments directed to legislative jurisdiction." DE 1973 at 26. Thus, for the same reasons that Plaintiffs failed to establish a prima facie case of specific personal jurisdiction over Defendants in any state or territory, the Court similarly holds that Plaintiffs have not established sufficient minimum contacts between Defendants and the states of Massachusetts or California, such that neither state may apply their substantive law extraterritorially in accordance with the Due Process Clause. Thus, Counts VII, VIII, XIII, XIV, and XV of the MPIC brought by Plaintiffs against Defendants outside of California and Massachusetts to which Plaintiffs seek to have California and Massachusetts law apply fail and are dismissed without prejudice. Because of this dismissal, a choice-of-law analysis is unnecessary as to all Defendants except one: Patheon Manufacturing Services, LLC ("Patheon").

As alleged, Patheon is a brand-name manufacturer subject to general personal jurisdiction in Massachusetts. MPIC ¶ 35. Therefore, at least as to Pantheon, the Court concludes that Plaintiffs have met their burden to allege a basis for personal jurisdiction and the Court must conduct a choice-of-law analysis for the State of Massachusetts. The Court is nonetheless unable to do so because this issue has received minimal attention in the parties' briefing. Plaintiffs merely contend, in a conclusory fashion, that any choice-of-law analysis will favor them, and Defendants, for their part, make the equally conclusory assertion that a choice-of-law analysis will favor them. Neither party has addressed or argued Massachusetts choice of law. The Court therefore expresses no opinion on Massachusetts choice-of-law principles and declines to dismiss Patheon on legislative-jurisdiction grounds at this juncture. In the event this issue is raised by either party in the future, the parties must argue the appropriate choice-of-law factors and must apply those factors to the facts of this case.

VIII. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that Brand-Name Manufacturer Defendants' Motion to Dismiss [DE 1585] is **GRANTED**.

1. All claims brought by Plaintiffs against Defendants in California courts fail for lack of personal jurisdiction and are **DISMISSED WITHOUT PREJUDICE AND WITH LEAVE TO AMEND** consistent with this Order.

2. All claims brought by Plaintiffs against Defendants, with the exception of Patheon Manufacturing Services, LLC, in Massachusetts courts fail for lack of personal jurisdiction and are **DISMISSED WITHOUT PREJUDICE AND WITH LEAVE TO AMEND** consistent with this Order.

3. All claims brought by Plaintiffs against Defendants in courts outside of California and Massachusetts are **DISMISSED WITHOUT PREJUDICE AND WITH LEAVE TO AMEND** consistent with this Order.

4. Leave to amend is granted as to the MPIC. At this time, the Court is not requiring any individual complaints or Short Form Complaints to be amended.

5. Under Pretrial Order # 36, Plaintiffs' repled Master Complaints are due 30 days after the Court issues its Order on Article III standing. DE 1346 at 4. The Court **AMENDS** that requirement in Pretrial Order # 36. Plaintiffs' repled Master Complaints are due 30 days after the Court issues its forthcoming Order on Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law. DE 1580. All other requirements in Pretrial Order # 36 remain in place.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 31st day of December, 2020.

Appendix A

1. Alaska

The Alaska Supreme Court and the Alaska intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Alaska law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Alaska Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

***13** There is no Alaska caselaw that explicitly addresses the issue of product identification. However, Alaska law dictates that a manufacturer "is strictly liable in tort when an article *he places* on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1194 (Alaska 1992) (quoting *Clary v. Fifth Ave. Chrysler Ctr.*, 454 P.2d 244, 247 (Alaska 1969)) (emphasis added). Under Alaska law, therefore, product identification must be alleged in order to maintain a products liability claim. However, Alaska does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. And, the Court is unaware of any Alaska caselaw indicating that those claims would be construed as products liability claims. The Alaska Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims. Thus, the Court must predict whether the Alaska Supreme Court would hold that Defendants owe a duty to Plaintiffs.

To determine whether a claim presents an actionable duty of care, Alaska courts look to:

> The foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost and prevalence of insurance for the risk involved.

D. S. W. v. Fairbanks N. Star Borough Sch. Dist., 628 P.2d 554, 555 (Alaska 1981) (quotation omitted). Alaska courts have stated that "[t]he most important single criterion for imposing a duty of care is foreseeability" and that "the legal relationship between individuals" is the overall focus of the duty question. *Bolieu v. Sisters of Providence in Wash.*, 953 P.2d 1233, 1235-36 (Alaska 1998).

After weighing these factors, the Court predicts that the Alaska Supreme Court would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. First, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *In re Darvocet*, 756 F.3d at 944 (citing Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1865 (2013) (hereinafter "Schwartz et al."). To impose a duty under Alaska law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171.

Further, the Court finds that the connection between Defendants' alleged conduct and Plaintiffs' alleged injuries is attenuated, given the absence of a relationship between the parties. Additionally, the burden to Defendants and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name manufacturers liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 377 (Iowa 2014) (noting that "extending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks"); *McNair v. Johnson & Johnson*, 241 W.Va. 26, 818 S.E.2d 852, 866 (2018) (explaining that "[i]f brand manufacturers become liable for injuries allegedly caused by generic drugs, significant litigation costs would be added to the price of new drugs to the disadvantage of consumers" and "the increase in litigation ... could stifle the development of new drugs").

***14** In sum, the Court predicts that the Alaska Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Alaska Law.

2. Arizona

The Arizona Supreme Court and the Arizona intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Arizona law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Arizona Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Arizona products liability law defines a "products liability action" as:

> [*A*]*ny action* brought against a manufacturer or seller of a product for damages for bodily injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, installation, preparation, assembly, testing, packaging, labeling, sale, use or consumption of any product, the failure to warn or protect against a danger or hazard in the use or misuse of the product or the failure to provide proper instructions for the use or consumption of any product.

Ariz. Rev. Stat. Ann. § 12-681 (2020) (emphasis added). Further, product identification is a "fundamental tenet" of Arizona products liability law. *Winsor v. Glasswerks PHX, L.L.C.*, 204 Ariz. 303, 63 P.3d 1040, 1049 (Ariz. Ct. App. 2003) (noting that Arizona law construes the reach of products liability to those involved in the chain of production or distribution of the product, but that Arizona courts have never "expanded liability to those entities who bear no causal connection to the production or distribution of the product").

Given the plain language of § 12-681, the Court predicts that the Arizona Supreme Court would find all of Plaintiffs' claims to be products liability claims, regardless of how they are characterized, and that such claims require product identification to be viable. For this reason, the Court predicts that the Arizona Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification. [10]

3. Arkansas

***15** The Arkansas Supreme Court and the Arkansas intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Arkansas law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Arkansas Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

In *Bell v. Pfizer, Inc.*, the Eighth Circuit predicted that the Arkansas Supreme Court would hold that Arkansas law does not support imposing liability on a brand-name manufacturer for a generic manufacturer's product. 716 F.3d at 1094. The court held that the plaintiffs' negligence-based claims for injuries caused by a product fell within the Arkansas Product Liability Act's broad definition of a "product liability action," making them products liability claims. *Id.* at 1092; *see* Ark. Code Ann. § 16-116-102(5) (2020) (defining "product liability action" as "all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of any product"). The court also noted that a basic requirement of a products liability action under Arkansas law is product identification. *Bell*, 716 F.3d at 1093. Thus, the court held the plaintiffs' claims against brand-name manufacturers failed for lack of product identification. *Id.* And for the sake of argument, the court held that even if the requirement of product identification was ignored, the claims would fail for lack of a duty as there was no Arkansas authority that supported extending "a duty of care to the customer of a competitor using a competing product." *Id.*

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Eighth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Arkansas Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. [11] The Court therefore predicts that the Arkansas Supreme Court would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Arkansas law.

4. Colorado

The Colorado Supreme Court and the Colorado intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Colorado law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Colorado Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

In *Sheeks v. American Home Products Corporation*, a Colorado District Court held that Colorado law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. No. 02CV337, 2004 WL 4056060, at *2 (Colo. Dist. Ct. Oct. 15, 2004). The court held that the plaintiffs' misrepresentation claims fell within the Colorado Product Liability Act's broad definition of a "product liability action," making them products liability claims. *See id.* at *1; *see also* Colo. Rev. Stat. Ann. § 13-21-401 (West 2020) (defining "[p]roduct liability action" as "*any action* brought against a manufacturer or seller of a product, *regardless of the substantive legal theory or theories upon which the action is brought*, for or on account of personal injury, death, or property damage caused by or resulting from ... [a] product") (emphasis added)).

***16** Further, the court noted that, "[u]nder Colorado statutory law, products liability is imposed on a 'manufacturer' of the product," which includes "those entities involved in the production of the product or otherwise in control [of] the production process." *Sheeks*, 2004 WL 4056060, at *1 (quoting *Yoder v. Honeywell, Inc.*, 900 F. Supp. 240, 246 (D. Colo. 1995), *aff'd*, 104 F.3d 1215 (10th Cir. 1997)). In other words, product identification is a requirement of a products liability action under Colorado law. Thus, the court held that the plaintiffs' claims failed for lack of product identification. *Id.*

The court declined to look at the plaintiffs' claim of negligent misrepresentation as distinct from their products liability claims. *Id.* at *2. The court noted for the sake of argument that even if it disregarded Colorado law and viewed the negligence misrepresentation claim as distinct, the claim would still fail because a brand-name manufacturer owed no duty to plaintiffs "to warn of a drug that it did not manufacture or supply." *Id.* The Court came to this conclusion after analyzing the factors

used to determine whether a duty exists under Colorado law. *See id.*; *see also Bailey v. Huggins Diagnostic & Rehab. Ctr., Inc.*, 952 P.2d 768, 772 (Colo. App. 1997) (listing the factors that Colorado courts consider to determine whether a duty exists as "whether harm is a reasonably foreseeable result of the act or omission under consideration" in addition to "the social utility of the defendant's activity; the magnitude of the burden guarding against the harm; the consequences of placing that burden on the defendant; and all other factors that would be relevant in weighing the competing individual and societal").

While the Court is not bound by the decisions of state district courts in making its *Erie* prediction, the Court finds the Colorado District Court's reasoning to be "reliable data tending convincingly to show" whether the Colorado Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. The Court therefore predicts that the Colorado Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and would otherwise fail for lack of a duty giving rise to liability under Colorado law.

5. Connecticut

The Connecticut Supreme Court and the Connecticut intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Connecticut law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Connecticut Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Sixth Circuit predicted that the Connecticut Supreme Court would hold that Connecticut law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See In re Darvocet*, 756 F.3d at 942. The court found that the plaintiffs' negligence-based claims were encompassed by the Connecticut Products Liability Act, making them products liability claims. *Id. see* Conn. Gen. Stat. § 52–572m(b) (defining a "product liability claim" as "all claims or actions brought for personal injury, death, or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product"). The court also noted that a requirement of a product liability action under Connecticut law is product identification. *In re Darvocet*, 756 F.3d at 942. Thus, the court held that the plaintiffs' claims failed for lack of product identification. *Id.*

***17** While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Sixth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Connecticut Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. The Court therefore predicts that the Connecticut Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification.

6. Delaware

The Delaware Supreme Court and the Delaware intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Delaware law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Delaware Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

In *Trower v. Janssen Pharmaceuticals, Inc.*, the federal District of Delaware predicted that the Delaware Supreme Court would hold that Delaware law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. No. 1:16-CV-00135-RGA, 2019 WL 1571834, at *4 (D. Del. Apr. 11, 2019). In its analysis, the court first noted that Delaware courts had held that Delaware products liability law requires product identification. *Id.* at *3 (citing *In re Benzene Litig.*, No. CIV.A.05C-09-020-JRS, 2007 WL 625054, at *6 (Del. Super. Ct. Feb. 26, 2007)). As to the question of whether brand-name manufacturers owe a generic consumer a duty, the court held that no Delaware law supports such a duty, and the court highlighted that "at least one Delaware court has expressed hesitation when pressured to make changes to traditional tort law in the product liability space." *Id.* (citing *Nutt v. A.C. & S. Co.*, 517 A.2d 690, 694 (Del. Super. Ct. 1986) (choosing to defer to the legislature rather than judicially expand the scope of liability)). Additionally, the court held that, "even if Delaware law provided some

basis for imposing liability for failure to warn on brand name manufacturers, it would be imprudent [for the federal court] to extend Delaware's law to that point while sitting in diversity." *Id.* at *4.

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the *Trower* court's reasoning to be "reliable data tending convincingly to show" whether the Delaware Supreme Court would find the theory of liability at issue to be viable. The Court therefore predicts that the Delaware Supreme Court either would construe all of Plaintiffs' claims as products liability claims that fail for lack of product identification or would rule that Plaintiffs' claims otherwise fail for lack of a duty giving rise to liability under Delaware law.

7. District of Columbia

The D.C. Court of Appeals and the D.C. intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under D.C. law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the D.C. Court of Appeals would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

D.C. products liability law requires product identification. *See Claytor v. Owens-Corning Fiberglas Corp.*, 662 A.2d 1374, 1381 (D.C. 1995) ("It is, of course, incumbent on the plaintiff in any product liability action to show that the defendant's product was the cause of his or her injuries."). However, D.C. does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any D.C. caselaw indicating that those claims would be construed as products liability claims. The D.C. Court of Appeals could consider Plaintiffs' negligence-based claims as distinct from products liability claims under D.C. law. As a result, the Court must predict whether the D.C. Court of Appeals would find that Defendants owe a duty to Plaintiffs.

***18** In determining whether a duty is owed, D.C. courts primarily look to the foreseeability of the harm, which is largely determined by the nature of the relationship between the parties. *See Hedgepeth v. Whitman Walker Clinic*, 22 A.3d 789, 794 (D.C. 2011). Whether a duty exists is "essentially a question of whether the policy of the law will extend the responsibility for the conduct to the consequences which have in fact occurred." *District of Columbia v. Cooper*, 483 A.2d 317, 321 (D.C. 1984) (quotation marks omitted).

After weighing the requisite factors, the Court predicts that the D.C. Court of Appeals would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. First, the generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). Additionally, the Court views the relationship between the brand-name manufacturers and generic consumers to be, at best, "at arms' length." *See Hedgepeth*, 22 A.3d at 794 (noting that generally "there is only a minimal duty—if any—owed to a party who is at arms' length"). The Court predicts that the D.C. Court of Appeals would not recognize a duty owed by Defendants to Plaintiffs. In sum, the Court predicts that D.C. Court of Appeals would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under D.C. law.

8. Hawaii

The Supreme Court of Hawaii and the Hawaii intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Hawaii law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Hawaii would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

In *Acoba v. General Tire, Inc.*, the Supreme Court of Hawaii stated that, under Hawaii products liability law, there is a "principle" that "a manufacturer owes a duty to warn regarding its *own product*, not regarding products it did not produce, sell, or control." 92 Hawai'i 1, 986 P.2d 288, 305 (1999). While Hawaii has no products liability statute that would subsume Plaintiffs' negligence-

based claims, the court's meaning in *Acoba* is clear: a manufacturer owes no duty to consumers of products it did not produce, sell, or control. Therefore, the Court predicts that the Supreme Court of Hawaii would not recognize a duty owed by Defendants to Plaintiffs. In sum, the Court predicts that the Supreme Court of Hawaii would hold that Plaintiffs' claims against Defendants fail for lack of a duty giving rise to liability under Hawaii Law.

9. Illinois

The Supreme Court of Illinois and the Illinois intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Illinois law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Illinois would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

***19** Three federal courts have predicted whether the Supreme Court of Illinois would hold that Illinois law supports imposing liability upon brand-name manufacturers. In *Dolin v. SmithKline Beecham Corp.*, the Northern District of Illinois held that the plaintiff's common-law negligence claims were distinct from her products liability claims. 62 F. Supp. 3d at 713. Consequently, the court analyzed the four *Simpkins* factors used to determine whether a duty is owed by brand-name manufacturers to generic consumers: "(1) the reasonable foreseeability of the injury; (2) the likelihood of the injury; (3) the magnitude of the burden guarding against the injury; and (4) the consequences of placing that burden on the defendant." *Id.* at 714–15 (quoting *Simpkins v. CSX Transportation, Inc.*, 358 Ill.Dec. 613, 965 N.E.2d 1092, 1097 (2012)). The court held that it was "entirely foreseeable" that negligence on the part of the brand-name manufacturer regarding the brand-name label could result in injury to generic consumers because the labels were required by law to be identical and defects later discovered could only be remedied by the brand-name manufacturer. *Id.* at 714.

The court further held that there was a strong likelihood that the brand-name manufacturer's negligence in the design or warning label of the drug would cause injury, that guarding against the injury alleged was "as simple as updating the warning label," and that there was nothing in the record to suggest the consequences of placing the burden on the defendant were large. *Id.* at 715. Thus, the court predicted that the Supreme Court of Illinois would conclude that the brand-name manufacturer owed a duty to the generic consumer giving rise to liability under Illinois law, and, as a result, the plaintiff's general negligence claim, negligent misrepresentation claim, and negligence-based products liability claims were deemed viable. *Id.* at 723–24. The Central District of Illinois, relying upon the *Dolin* court's reasoning, came to the same conclusion. *See Garner*, 2017 WL 6945335, at *6–9.

In *In re Darvocet*, the Sixth Circuit explicitly rejected the *Dolin* court's reasoning. 756 F.3d at 944. The court explained that, while Illinois has no products liability statute that encompassed the plaintiffs' negligence-based claims, Illinois caselaw dictated that the claims "would be construed as products liability claims and fail for lack of product identification." *Id*; *see York v. Lunkes*, 189 Ill.App.3d 689, 136 Ill.Dec. 954, 545 N.E.2d 478, 480 (1989) (holding that, under Illinois law, a plaintiff must "identify the supplier of the product and establish a causal connection between the injury and the product"); *Smith v. Eli Lilly & Co.*, 137 Ill.2d 222, 148 Ill.Dec. 22, 560 N.E.2d 324, 328 (1990) ("[I]t is obvious that to hold a producer, manufacturer, or seller liable for injury caused by a particular product, there must first be proof that the defendant produced, manufactured, sold, or was in some way responsible for the product") (quotation marks omitted).

The Sixth Circuit further held that, even if the Supreme Court of Illinois construed the plaintiffs' misrepresentation claims as distinct from products liability claims, the *Simpkins* duty factors do not support recognizing a duty owed by brand-name manufacturers to generic consumers. *In re Darvocet*, 756 F.3d at 944. In applying the factors, the court found that the generic consumers' injuries were "not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control," and that using "these laws as the basis of supplying the duty element for tort liability stretches foreseeability too far." *Id.*; *see* Schwartz et al. at 1865. The Sixth Circuit also held that the *Dolin* court "failed to properly account for the magnitude of the brand manufacturers' burden of guarding against the injury; and the consequences of placing that burden on the brand manufacturers." *In re Darvocet*, 756 F.3d at 944. The court reasoned that "[c]ourts in the majority note the traditional reticence against imposing liability on a manufacturer for injuries caused by their competitor's products."

Id. And the court highlighted the "grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher brand name drugs and fewer innovative drugs." *Id.*

***20** The Court finds the reasoning of the Sixth Circuit in *In re Darvocet* to be sound and more persuasive than the reasoning of the *Dolin* and *Garner* courts. While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Sixth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Supreme Court of Illinois would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. The Court therefore predicts that the Supreme Court of Illinois would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Illinois law.

10. Maine

The Maine Supreme Judicial Court and the Maine intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Maine law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Maine Judicial Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Maine Supreme Judicial Court has noted that there is "no authority" to suggest that "the supplier of a safe product has a duty to warn against another supplier's dangerous product." *Bouchard v. Am. Orthodontics*, 661 A.2d 1143, 1145 (Me. 1995). Further, the federal District Court of Maine held that, under Maine law, "[a] manufacturer or seller owes a duty to exercise reasonable care to foreseeable users of its products." *Doe v. Solvay Pharm., Inc.*, 350 F. Supp. 2d 257, 263 (D. Me. 2004), *aff'd*, 153 F. App'x 1 (1st Cir. 2005). Pursuant to this caselaw and the fact that, given there are no indications to the contrary, it is presumed that Maine would adopt the majority view requiring product identification for products liability claims.

However, Maine does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Nor is the Court aware of any caselaw indicating that Maine courts would construe those claims as products liability. The Maine Supreme Judicial Court could consider Plaintiffs' negligence-based claims distinct from products liability claims under Maine law. However, based on the same caselaw the Court relied upon in holding that the Maine Supreme Judicial Court would require product identification, the Court also predicts that the Maine Supreme Judicial Court would not recognize a duty owed by brand-name manufacturers to generic consumers. *See Bouchard*, 661 A.2d at 1145 (holding that "the supplier of a safe product has no duty to warn against another supplier's dangerous product"); *Doe*, 350 F. Supp. 2d at 263 (explaining that "[a] manufacturer or seller owes a duty to exercise reasonable care to foreseeable users of its products").

In sum, the Court predicts that the Maine Supreme Judicial Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Maine law.

11. Maryland

The Maryland Court of Appeals and the Maryland intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Maryland law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Maryland Court of Appeals would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

In *Foster v. American Home Products Corp.*, the Fourth Circuit predicted that the Maryland Court of Appeals would hold that Maryland law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. 29 F.3d 165, 172 (4th Cir. 1994). Specifically, the court held that, under Maryland law, a plaintiff must plead product identification and that the plaintiffs brought negligence-based claims merely as an attempt to "circumvent the necessity that a defendant be shown to have manufactured the product that caused an injury prior to being held liable for such injury." *Id.* at 168; *see also Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 92 (D. Md. 1989) (noting that it is "axiomatic" that the plaintiff must "prove that the defendant manufacturer made the product that caused plaintiff's injury"); *Jensen v. Am. Motors Corp.*, 50 Md.App.

226, 437 A.2d 242, 247 (Md. Ct. Spec. App. 1981) ("*Regardless of the recovery theory*, the plaintiff in product litigation must satisfy three basics from an evidentiary standpoint: (1) the existence of a defect; (2) the attribution of the defect to the seller; and (3) a causal relation between the defect and the injury.") (emphasis added). The Fourth Circuit, thus, predicted that that the Maryland Court of Appeals would construe all of the plaintiffs' claims as products liability claims that failed for lack of product identification. *Foster*, 29 F.3d at 168.

***21** Further, the court held that, even if it disregarded Maryland law and construed the plaintiffs' negligence-based claims as distinct from products liability claims, Maryland law would not support recognizing a duty owed by brand-name manufacturers to generic consumers. *Id.* at 171. The court explained that "to impose a duty... would be to stretch the concept of foreseeability too far" considering the complete absence of a relationship between brand-name manufacturers and generic consumers. *See id.*

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Fourth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Maryland Court of Appeals would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. [12] In sum, the Court therefore predicts that the Maryland Court of Appeals would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Maryland law.

12. Michigan

The Michigan Supreme Court and the Michigan intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Michigan law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Michigan Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Sixth Circuit predicted that the Michigan Supreme Court would hold that Michigan law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See In re Darvocet,* 756 F.3d at 946–47. In making this prediction, the Sixth Circuit first held that Michigan products liability law requires product identification. *See id.*; *see also Abel v. Eli Lilly & Co.*, 418 Mich. 311, 343 N.W.2d 164, 170 (1984) (holding that "the threshold requirement of any products liability action is identification of the injury-causing product and its manufacturer"). The court also found that Michigan products liability law does not clearly "foreclose or permit common law negligence actions against non-manufacturers for misrepresentations based on injuries from products"; thus, the court had to predict whether brand-name manufacturers owed generic consumers a duty of care giving rise to liability for their alleged misrepresentations. *In re Darvocet*, 756 F.3d at 947.

The court explained that whether a defendant owes a plaintiff a duty under Michigan law depends on "the relationship between the parties, the nature and foreseeability of the risk, and any other considerations that may be relevant on the issue." *Id.* (quoting *Buczkowski v. McKay*, 441 Mich. 96, 490 N.W.2d 330, 333 (1992)). In analyzing these factors, the court found that the parties had no relationship, that the generic consumers' injuries were "not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control," and that there were "grave health policy consequences associated with recognizing brand manufacturer liability in these situations, including high priced brand name drugs and fewer innovative drugs." *Id.* (quoting Schwartz et al. at 1870–71). Thus, the court predicted that the Michigan Supreme Court would not recognize a duty owed by brand-name manufacturers to the generic consumers. *Id.*

***22** While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Sixth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Michigan Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Michigan Supreme Court would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Michigan law.

13. Minnesota

The Minnesota Supreme Court and the Minnesota intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Minnesota law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Minnesota Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Minnesota Court of Appeals case of *Flynn v. American Home Products Corp.*, 627 N.W.2d 342, 344 (Minn. App. 2001) is instructive. In *Flynn*, a generic drug consumer brought misrepresentation claims against brand-name drug manufacturers. 627 N.W.2d at 344. The court held that the brand-name manufacturers did not owe the generic consumers a duty because "Minnesota common law... requires a stronger relationship and a direct communication" between a defendant and a plaintiff in order to find that a duty exists. *Id.* at 350. As the plaintiff "did not purchase or use [the brand-name manufacturers'] product ... there was no direct relationship between them, let alone a fiduciary relationship that gave rise to a duty." *Id.*

Further, the Eighth Circuit has predicted, relying upon the reasoning in *Flynn*, that generic consumers' products liability claims against brand-name manufacturers fail for lack of product identification and legal duty. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612-14 (8th Cir. 2009), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 564 U.S. 604, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011), *and opinion vacated in part, reinstated in part*, 658 F.3d 867 (8th Cir. 2011); *see also Magnuson v. Rupp Mfg., Inc.,* 285 Minn. 32, 171 N.W.2d 201, 206 (1969) (noting that Minnesota products liability law requires the plaintiff to prove that the "dangerous condition of the defendant's product" caused the plaintiff's injuries).

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the reasoning of the Eighth Circuit, as well as that of the Minnesota Court of Appeals in *Flynn*, to be "reliable data tending convincingly to show" whether the Minnesota Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. The Court therefore predicts that the Minnesota Supreme Court would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Minnesota law.

14. Mississippi

The Supreme Court of Mississippi and the Mississippi intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Mississippi law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Mississippi would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Fifth Circuit predicted that the Supreme Court of Mississippi would hold that Mississippi law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Lashley*, 750 F.3d at 476. The court noted that that Mississippi products liability claims require product identification and, additionally, that the Mississippi Products Liability Act ("MLPA") applies "in any action for damages caused by a product." *Id.* at 476–77 (quoting Miss. Code Ann. § 11–1–63 (2020)); *see also Monsanto Co. v. Hall*, 912 So. 2d 134, 136–37 (Miss. 2005) (holding that a required element of a products liability claim under Mississippi law is product identification). Thus, the Fifth Circuit construed all of the plaintiff's negligence-based claims as products liability claims under the MLPA that failed for lack of product identification. *Lashley*, 750 F.3d at 476-77.

***23** While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Fifth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Supreme Court of Mississippi would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. [13] The Court therefore predicts that the Supreme Court of Mississippi would hold that Plaintiffs' claims fail for lack of product identification.

15. Missouri

The Supreme Court of Missouri and the Missouri intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Missouri law. Therefore, the Court must make a

prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Missouri would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

Missouri products liability law requires product identification. *See Ford v. GACS, Inc.*, 265 F.3d 670, 680 (8th Cir. 2001) (holding that "[t]he common thread among Missouri products liability cases is that an entity must have 'plac[ed] a defective product in the stream of commerce' ") (quoting *Bailey v. Innovative Mgmt. & Inv., Inc.*, 916 S.W.2d 805, 807-08 (Mo. Ct. App. 1995)); *In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 3610237, at *2 (E.D. Ky. Aug. 21, 2012) (finding that, under Missouri law, "[t]here is no theory of product liability under which a defendant can be held liable for an injury caused by a product it did not sell, manufacture, or otherwise supply to the plaintiff"), *aff'd on other grounds*, 756 F.3d 917 (6th Cir. 2014); *Johnson v. Auto Handling Corp.,* 523 S.W.3d 452, 466 (Mo. 2017) (en banc) (holding that, in negligent manufacture, design, or warning products liability cases, Missouri law "requires the jury to consider whether the defendant manufactured the product"); *City of St. Louis v. Benjamin Moore & Co.*, 226 S.W.3d 110, 115 (Mo. 2007) (holding that, "where the plaintiff seeks to hold the defendants liable on the basis that their products caused harm to the plaintiff, the identification requirement must be satisfied").

However, Missouri does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Missouri caselaw indicating that those claims would be construed as products liability claims. The Supreme Court of Missouri could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Missouri law. As a result, the Court must predict whether the Supreme Court of Missouri would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty is owed, Missouri courts weigh "the foreseeability of the injury, the likelihood of the injury, the magnitude of the burden of guarding against it, and the consequences of placing that burden on the defendant." *Bunker v. Ass'n of Mo. Elec. Coops.*, 839 S.W.2d 608, 611 (Mo. Ct. App. 1992). "The common denominator that must be present is the existence of a relationship between the plaintiff and defendant that the law recognizes as the basis of a duty of care." *Id.* Further, Missouri courts look "to the body of statutes, rules, principles and precedents which make up the law." *Kopoian v. George W. Miller & Co.*, 901 S.W.2d 63, 68 (Mo. Ct. App. 1995) (quotation marks omitted). "Where no duty is indicated by Missouri statute, case law, or otherwise, a fundamental prerequisite to establishing negligence is absent." *Ford*, 265 F.3d at 682.

***24** After weighing the requisite factors, the Court predicts that the Supreme Court of Missouri would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. First, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). To impose a duty under Missouri law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171.

Further, the Court finds that the burden to Defendants and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name competitors liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (finding that "extending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks"); *McNair*, 818 S.E.2d at 866 (explaining that "[i]f brand manufacturers become liable for injuries allegedly caused by generic drugs, significant litigation costs would be added to the price of new drugs to the disadvantage of consumers" and "the increase in litigation ... could stifle the development of new drugs").

In sum, the Court predicts that the Supreme Court of Missouri would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Missouri law.

16. Montana

The Montana Supreme Court and the Montana intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Montana law. Therefore, the Court must make a

prediction using all "reliable data tending convincingly to show" whether the Montana Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Montana products liability law requires product identification. *See Schelske v. Creative Nail Design, Inc.*, 280 Mont. 476, 933 P.2d 799, 803 (1997) (holding that, to proceed with a prima facie claim of products liability, the plaintiff must allege product identification and that, further, the "the defect existed when it left the hands of the defendant"). However, Montana does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Montana caselaw indicating that those claims would be construed as products liability claims. The Montana Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Montana law. As a result, the Court must predict whether the Montana Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty is owed, Montana courts consider whether the injuries were "reasonably foreseeable" as well as various policy factors, including "the moral blame attributable to the defendant's conduct; the prevention of future harm; the extent of the burden placed on the defendant; the consequences to the public of imposing such a duty; and the availability of insurance for the risk involved." *Hinkle v. Shepherd Sch. Dist. No. 37*, 322 Mont. 80, 93 P.3d 1239, 1244 (2004).

After weighing the requisite factors, the Court predicts that the Montana Supreme Court would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. First, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). To impose a duty under Montana law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171. Further, the Court finds that the burden to Defendants and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name competitors liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (concluding that "extending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks"); *McNair*, 818 S.E.2d at 866 (explaining that "[i]f brand manufacturers become liable for injuries allegedly caused by generic drugs, significant litigation costs would be added to the price of new drugs to the disadvantage of consumers" and "the increase in litigation ... could stifle the development of new drugs").

***25** In sum, the Court predicts that the Supreme Court of Montana Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Montana law.

17. Nebraska

The Nebraska Supreme Court and the Nebraska intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Nebraska law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Nebraska Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

The Sixth Circuit predicted that the Nebraska Supreme Court would hold that Nebraska law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See In re Darvocet,* 756 F.3d at 948–49. The court determined that the plaintiffs' negligence-based claims were encompassed by Nebraska's products liability statute, making them products liability claims. *Id.* at 948; *see also* Neb. Rev. Stat. § 25-21,180 (2020) (defining a "product liability action" as "any action brought against a manufacturer, seller, or lessor of a product, regardless of the substantive legal theory or theories upon which the action is brought, for or on account of personal injury [or] death"). The court also noted that a requirement of a product liability action under Nebraska law is product identification. *In re Darvocet*, 756 F.3d at 948; *see* Neb. Rev. Stat. § 25-21,180 (2020) (limiting liability to "the manufacturer of the product or part thereof claimed to be defective"). Thus, the court predicted that the Nebraska Supreme Court would construe all of the plaintiffs' claims as products liability claims that failed for lack of product identification. *In re Darvocet*, 756 F.3d at 948.

The court also predicted that, even if the Nebraska Supreme Court characterized the plaintiffs' negligence-based claims as distinct from products-liability claims, the Nebraska Supreme Court would not recognize a duty owed by the defendants to the plaintiffs. *Id.* The court explained that, in order to determine whether a defendant owes a duty, Nebraska courts look to the Restatement (Third) of Torts. *Id* (citing Restatement (Third) of Torts § 7 (Am. Law Inst. 2010)). The court further explained that, "[u]nder that regime, actors must 'exercise reasonable care' when their conduct creates a risk of harm, but courts may decide a defendant has 'no duty' in exceptional cases, when a countervailing policy warrants denying or limiting liability." *Id.* (quoting *A.W. v. Lancaster Cty. Sch. Dist. 0001*, 280 Neb. 205, 784 N.W.2d 907, 918 (2010)). The court determined that the brand-name manufacturers' conduct "did not create the risk of harm that caused plaintiffs' injuries, rather the Congressional and Nebraska state laws designed to increase the availability of generic drugs did." *Id.*; *see* Schwartz et al., at 1870–71. The court further determined that there were "grave health policy consequences associated with recognizing brand manufacturer liability in these situations, including high priced brand name drugs and fewer innovative drugs." *In re Darvocet*, 756 F.3d at 948. The court concluded that "the potential ramifications for Nebraskans' health and welfare" made the case exceptional and warranted denying liability. *Id.*

***26** While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Sixth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Nebraska Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Nebraska Supreme Court would hold that Plaintiffs' claims fail for lack of product identification and duty giving rise to liability under Nebraska Law.

18. Nevada

The Supreme Court of Nevada and the Nevada intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Nevada law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Nevada would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The federal District Court of Nevada has twice predicted that the Supreme Court of Nevada would hold that Nevada law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Baymiller v. Ranbaxy Pharm., Inc.*, 894 F. Supp. 2d 1302, 1310 (D. Nev. 2012); *Moretti v. Wyeth, Inc.*, No. 2:08-CV-00396-JCMGWF, 2009 WL 749532, at *3 (D. Nev. Mar. 20, 2009). In *Moretti*, the court determined that, under Nevada products liability law, a plaintiff must allege product identification. *Moretti*, 2009 WL 749532, at *5; *see Allison v. Merck & Co., Inc.*, 110 Nev. 762, 878 P.2d 948, 952 (1994) (holding that a plaintiff must establish that his injury was "caused by a defect in the product, and that such defect existed when the product left the hands of the defendant"). Thus, the court predicted that the Supreme Court of Nevada would hold that plaintiff's products liability claims would fail for lack of product identification. *Moretti*, 2009 WL 749532, at *5.

The district court also noted that, for a duty to exist, Nevada law "requires, at a minimum, some form of relationship between the parties." *Id.* at *3. The court found that no such relationship existed between the plaintiff who had consumed a generic drug and the brand-name manufacturer defendant. *Id*. Thus, the court predicted that, even if the Supreme Court of Nevada characterized the plaintiffs' fraud and negligence-based claims as distinct from products-liability claims, the Supreme Court would not recognize a duty owed by the defendant to the plaintiff. *Id.*; *see Baymiller*, 894 F. Supp. 2d at 1309 (holding that the brand-name manufacturer did not owe the plaintiff a duty of care because the brand-name manufacturer did not manufacture the drug that purportedly injured the plaintiff).

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the District Court of Nevada's reasoning to be "reliable data tending convincingly to show" whether the Supreme Court of Nevada would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Supreme Court of Nevada would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Nevada Law.

19. New Hampshire

The New Hampshire Supreme Court and the New Hampshire intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under New Hampshire law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the New Hampshire Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

***27** New Hampshire law requires product identification. *See Univ. Sys. of N.H. v. U.S. Gypsum Co.*, 756 F. Supp. 640, 653 (D.N.H. 1991) (explaining that the "imposition of liability depends upon the plaintiff[ ] proving that the defendant manufacturer made the product that caused the plaintiff's injury"); *cf. MacCleery v. T.S.S. Retail Corp.*, 882 F. Supp. 13, 16 (D.N.H. 1994) (holding that a manufacturer who was not involved in the design, manufacture, or distribution of the product that caused the plaintiff's injury "has not ... engaged in any conduct for which, as a matter of law, it could be directly liable"). However, New Hampshire does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. And, the Court is unaware of any New Hampshire caselaw indicating that those claims would be construed as products liability claims. The New Hampshire Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under New Hampshire law. As a result, the Court must predict whether the New Hampshire Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty exists, New Hampshire courts balance "the societal interest involved, the severity of the risk, the burden upon the defendant, the likelihood of occurrence and the relationship between the parties." *Williams v. O'Brien*, 140 N.H. 595, 669 A.2d 810, 813 (1995). Further, "the balance weighs in favor of the plaintiff only when a special relationship indicating heightened reliance exists" or other "special circumstances" are present. *Id.*

Defendants and Plaintiffs have no relationship, let alone the required "special relationship," and the Court is unaware of any other "special circumstances" in this case that would warrant imposing liability upon Defendants. Therefore, the Court predicts that the New Hampshire Supreme Court would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs.

In sum, the Court predicts that the New Hampshire Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under New Hampshire law.

20. New Mexico

The New Mexico Supreme Court and the New Mexico intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under New Mexico law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the New Mexico Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

New Mexico products liability law requires product identification. *See Huber v. Armstrong World Indus., Inc.*, 930 F. Supp. 1463, 1465 (D.N.M. 1996) (holding that the plaintiff failed to produce sufficient evidence that he was injured by a product manufactured by any of the defendants); *see also Tenney v. Seven-Up Co.*, 92 N.M. 158, 584 P.2d 205, 206 (N.M. App. 1978) (holding that, in a products liability case, a plaintiff must prove "the product was defective when it left the *hands of the defendants*") (emphasis added). However, New Mexico does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any New Mexico caselaw indicating that those claims would be construed as products liability claims. The New Mexico Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under New Mexico law. As a result, the Court must predict whether the New Mexico Supreme Court would hold that Defendants owe a duty to Plaintiffs.

When determining the existence of a duty, New Mexico courts "must articulate specific policy reasons, unrelated to foreseeability considerations, when deciding whether a defendant does or does not have a duty or that an existing duty should be limited." *Rodriguez v. Del Sol Shopping Ctr. Assocs., L.P.*, 326 P.3d 465, 474 (N.M. 2014). "Only '[i]n exceptional cases, when

an articulated countervailing principle or policy warrants denying or limiting liability in a particular class of cases, a court may decide that the defendant has no duty or that the ordinary duty of reasonable care requires modification.' " *Id.* at 471 (quoting Restatement (Third) of Torts § 7(b) (Am. Law Inst. 2010)).

***28** The Court predicts that the New Mexico Supreme Court would follow the majority view and determine that Defendants do not owe Plaintiffs a duty of care. As the Sixth Circuit explained when interpreting Nebraska law, which also adheres to the Restatement (Third) of Torts, the brand-name manufacturers' conduct "did not create the risk of harm that caused plaintiffs' injuries, rather the Congressional and Nebraska state laws designed to increase the availability of generic drugs did." *See In re Darvocet*, 756 F.3d at 948; *see also* Schwartz et al., at 1870–71. Additionally, there are "grave health policy consequences associated with recognizing brand manufacturer liability in these situations, including high priced brand name drugs and fewer innovative drugs." *See In re Darvocet*, 756 F.3d at 948. The potential health and welfare ramifications of recognizing such a duty make the case "exceptional" and warrant denying liability. *Id.*

In sum, the Court predicts that the New Mexico Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under New Mexico law.

21. New York

The New York Court of Appeals and the New York intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under New York law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the New York Court of Appeals would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Six federal courts and two New York state trial courts have held that Plaintiffs' theory of liability is inconsistent with New York law because a generic consumer's claims against brand-name manufacturers fail for lack of product identification or a duty triggering liability. *See In re Darvocet*, 756 F.3d at 949; *Montero v. Teva Pharm. USA Inc.*, No. 19 CIV. 9304 (AKH), 2019 WL 6907467, at *1 (S.D.N.Y. Dec. 4, 2019); *Rosser v. Sanofi-Aventis*, No. 17-CV-2396 (VSB), 2018 WL 4080351, at *4 (S.D.N.Y. Aug. 26, 2018); *In re Zofran*, 261 F. Supp. 3d 62, 78–79 (D. Mass. 2017); *Coleson v. Janssen Pharm., Inc.*, 251 F. Supp. 3d 716, 720-23 (S.D.N.Y. 2017); *Goldych v. Eli Lilly & Co.*, No. 5:04CV1477(GLS/GJD), 2006 WL 2038436, at *6 (N.D.N.Y July 19, 2006); *Preston v. Janssen Pharm., Inc.*, No. 158570/17, 2018 WL 5017045, at *3 (N.Y. Sup. Ct. Oct. 12, 2018); *Weese v. Pfizer, Inc.*, No. No. 153742/12, 2013 WL 5691993, at *2–3 (N.Y. Sup. Ct. Oct. 08, 2013).

In *Goldych v. Eli Lilly & Co.*, the Northern District of New York explained that New York law "requires a plaintiff seeking recovery for an injury caused by a defective product to prove that the defendant manufactured the product." 2006 WL 2038436, at *6; *see also Rastelli v. Goodyear Tire & Rubber Co.*, 79 N.Y.2d 289, 582 N.Y.S.2d 373, 591 N.E.2d 222, 225 (1992) (holding that "a plaintiff may recover in strict products liability or negligence when a manufacturer fails to provide adequate warnings regarding the use of *its* product") (emphasis added). The court reasoned that, although the plaintiff asserted alternative theories, she had effectively brought a products liability suit and could not "circumvent the requirements of product liability law." *Goldych*, 2006 WL 2038436, at *6. Thus, the court predicted that the New York Court of Appeals would hold that the plaintiff's products liability claims failed for lack of product identification. *Id.*

Additionally, in *Weese v. Pfizer, Inc.*, a New York trial court explained that "[i]t is to be expected that [the brand-name manufacturer] has a duty in connection with its own products and labels." 2013 WL 5691993, at *2. However, the court further held that the "duty should not extend to products and labeling over which it has no control, even if those products and labels mirrors its own, because it has done nothing toward putting them in the hands of consumers." *Id*. Thus, the court held that the brand-name manufacture owed no duty to generic consumers. *Id.* at *3.

***29** While the Court is not bound by the decisions of federal district courts or state trial courts in making its *Erie* prediction, the Court finds the reasoning in *Goldych* and *Weese* to be "reliable data tending convincingly to show" whether the New York

Court of Appeals would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. [14] In sum, the Court therefore predicts that the New York Court of Appeals would hold that Plaintiffs' claims fail for lack of product identification or duty giving rise to liability under New York Law.

22. North Carolina

The North Carolina Supreme Court and the North Carolina intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under North Carolina law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the North Carolina Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

Four federal courts have held that Plaintiffs' theory of liability is inconsistent with North Carolina law because a generic consumer's claims against brand-name manufacturers fail for lack of product identification. *See In re Darvocet*, 756 F.3d at 949–950; *Perdue v. Wyeth Pharm., Inc.*, 209 F. Supp. 3d 847, 854 (E.D.N.C. 2016); *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643, 646 (W.D.N.C. 2010); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 634 (E.D.N.C. 2009). In *Couick v. Wyeth, Inc.*, the Western District of North Carolina held that, although the plaintiff's claims were "masked in various legal theories," they were "premised on a single claim of product liability" and clearly fell within North Carolina's definition of a "product liability action." 691 F. Supp. 2d at 645; *see* N.C. Gen. Stat. Ann. § 99B-1 (2020) (defining a "product liability action" to include "any action brought for or on account of personal injury, death or property damage caused by or resulting from... any product"). The court also noted that North Carolina products liability law requires product identification. *See Couick*, 691 F. Supp. 2d at 645; *see also Stoddard*, 630 F. Supp. 2d at 634 ("[U]nder North Carolina law a manufacturer of a brand name pharmaceutical may not be held liable for injuries stemming from the use of another manufacturer's generic bioequivalent."). Thus, the court held that the plaintiff's claims failed for lack of product identification. *Couick*, 691 F. Supp. 2d at 645.

The court also held that the plaintiff's claims failed for lack of a duty owed by the brand-name manufacturers to generic consumers. *See id.* at 646. In making this determination, the court reasoned that "[i]mposing a duty upon the name-brand manufacturers for alleged injuries sustained by a product they did not manufacturer would 'stretch the concept of foreseeability too far.' " *Id.* (quoting *Foster*, 29 F.3d 165 at 171).

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Couick* to be "reliable data tending convincingly to show" whether the North Carolina Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. [15] In sum, the Court therefore predicts that the North Carolina Supreme Court would hold that Plaintiffs' claims fail for lack of product identification or, alternatively, for lack of a duty giving rise to liability under North Carolina Law.

23. North Dakota

***30** The North Dakota Supreme Court and the North Dakota intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under North Dakota law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the North Dakota Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

North Dakota products liability law requires product identification. *See Reagan v. Hi-Speed Checkweigher Co.*, 30 F.3d 947, 948 (8th Cir. 1994) (explaining that "a plaintiff must prove that there was a defect in the defendant's product or its design that was a proximate cause of his or her injuries"); *Morrison v. Grand Forks Hous. Auth.*, 436 N.W.2d 221, 224 (N.D. 1989) (stating that, to recover under a products liability action, "the plaintiff must prove there was a 'defect' in the defendant's product"). However, North Dakota law considers Plaintiffs' negligence-based claims distinct from products liability claims. *See Mauch v. Mfrs. Sales & Serv., Inc.*, 345 N.W.2d 338, 345 (N.D. 1984) (holding that "recovery sought under a negligent failure-to-warn

theory and recovery sought under a products-liability theory... are two separate and distinct theories of recovery"). As a result, the Court must predict whether the North Dakota Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty is owed, North Dakota courts "have focused on either the foreseeability of the injury or the nature of the relationship between the parties." *Palmer v. 999 Quebec, Inc.*, 874 N.W.2d 303, 309 (N.D. 2016). In this case, regardless of whether the Court focuses on the foreseeability of Plaintiffs' injuries or the nature of the relationship between Plaintiffs and Defendants, the Court predicts that the North Dakota Supreme Court would not recognize a duty owed by Defendants to Plaintiffs. There is no relationship between the parties. Additionally, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). To impose a duty under North Dakota law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171.

In sum, the Court predicts that the North Dakota Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under North Dakota law.

24. Oklahoma

The Supreme Court of Oklahoma and the Oklahoma intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Oklahoma law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Oklahoma would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Federal courts have consistently held that Plaintiffs' theory of liability is not viable under Oklahoma law. *See Schrock*, 727 F.3d at 1281–82; *accord In re Darvocet*, 756 F.3d 917, 950–51 (6th Cir. 2014); *In re Zofran*, 261 F. Supp. 3d 62, 79-80 (D. Mass. 2017). The Tenth Circuit noted that Oklahoma law requires "a relationship between the defendant company and the product at issue" for products liability claims based on theories of strict liability and negligence. *Schrock*, 727 F.3d at 1281; *see also Kirkland v. Gen. Motors Corp.*, 521 P.2d 1353, 1363 (Okla. 1974) (holding that, to prevail on a strict liability claim for a defective product, a plaintiff must show that the product was defective when it left the defendant's "possession and control"); *Spence v. Brown–Minneapolis Tank, Co.*, 198 P.3d 395, 401 (Okla. Civ. App. 2008) (rejecting a plaintiff's negligence claim because the defendant "had nothing to do with the manufacture" of the product at issue and did not "occupy a relationship which gives rise to a legal obligation ... for the benefit of the" plaintiff). Without such a relationship, there can be no duty to warn triggering liability on the part of brand-name manufacturers. *Schrock*, 727 F.3d at 1282-83. The court found no recognized relationship between the generic consumers and brand-name manufacturers. *Id.* at 1283. Based on that determination and the fact that every federal circuit court to address the plaintiffs' theory of liability had rejected it, the court predicted that Supreme Court of Oklahoma would hold that the plaintiffs' claims failed for lack of a duty owed by brand-name manufacturers to generic consumers. *Id.* at 1285-86.

***31** While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Tenth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Supreme Court of Oklahoma would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Supreme Court of Oklahoma would hold that Plaintiffs' claims fail for lack of a duty.

25. Oregon

The Oregon Supreme Court and the Oregon intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Oregon law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Oregon Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The federal District of Oregon predicted that the Oregon Supreme Court would hold that Oregon law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1120 (D. Or. 2012). The court held that Oregon's products liability statute "includes all theories a plaintiff may bring in an action based on a product defect." *Id*. at 1121; *see* Or. Rev. Stat. Ann. § 30.900 (2020) (defining "product liability civil action" as "a civil action brought against a manufacturer, distributor, seller, or lessor of a product for damages for personal injury, death, or property damage arising out of ... any defect, failure to warn, or failure to properly instruct in the use of a product"). The court also noted that, "[u]nder Oregon's product liability law, the name-brand defendants cannot be found liable for plaintiffs' injuries because plaintiffs cannot show that their injuries resulted from the use of the name-brand manufacturers' product." *Phelps*, 857 F. Supp. 2d at 1120 (citing *McEwen v. Ortho Pharm. Corp.*, 270 Or. 375, 528 P.2d 522, 538 (1974) (holding that the manufacturer owed a duty to disclose risks inherent in the use of its product)). Thus, the court held that all of the plaintiff's claims, whether based in a theory of negligence or strict liability, were products liability claims that failed for lack of product identification. *Id.* at 1122.

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Phelps* to be "reliable data tending convincingly to show" whether the Oregon Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Oregon Supreme Court would hold that Plaintiffs' claims fail for lack of product identification.

26. Pennsylvania

The Supreme Court of Pennsylvania and the Pennsylvania intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Pennsylvania law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Pennsylvania would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Eastern District of Pennsylvania predicted that the Supreme Court of Pennsylvania would hold that Pennsylvania law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 539 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008), *vacated and remanded on other grounds*, 556 U.S. 1101, 129 S.Ct. 1578, 173 L.Ed.2d 672 (2009). The court noted that "an essential and elementary characteristic" of Pennsylvania products liability law is that it requires "that the defendant manufacture or sell the product in question." *Id.* at 541 (citing *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 891 (1996) (holding that a products liability claim can only be brought against "a manufacturer" of the drug in question)). Further, after considering the factors that Pennsylvania courts examine to determine whether a duty exists, the court predicted that the Supreme Court of Pennsylvania would not recognize a duty owed by brand-name manufacturers to generic consumers. *Id.*; *see Althaus v. Cohen*, 562 Pa. 547, 756 A.2d 1166, 1169 (2000) (listing the factors as: "(1) the relationship between the parties; (2) the social utility of the actor's conduct; (3) the nature of the risk imposed and foreseeability of the harm incurred; (4) the consequences of imposing a duty upon an actor; and (5) the overall public interest in the proposed solution"). The court held that to impose a duty " 'would be to stretch the concept of foreseeability too far,' as [the brand-name manufacturer] cannot reasonably expect that consumers will rely on information they provide when actually ingesting another company's drug." *Colacicco*, 432 F. Supp. 2d at 541 (quoting *Foster*, 29 F.3d at 171). The court also held that it would be unfair to impose a duty upon the brand-name manufacturer when it did benefit from the sale of the generic drug and had "no control over the manufacturing or labeling" of the drug, "yet it bore the expense of developing the [brand-name drug] from which the [generic manufacturer] materially benefits." *Id.* (citing *Foster*, 29 F.3d at 170). Additionally, the court highlighted the importance of not "unduly burden[ing] the pharmaceutical industry with unfettered liability" so as to avoid hindering innovation. *Id.* at 542.

***32** While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Colacicco* to be "reliable data tending convincingly to show" whether the Supreme Court of Pennsylvania would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Supreme Court of Pennsylvania would hold that Plaintiffs' claims fail for lack of a duty triggering liability under Pennsylvania law.

27. Puerto Rico

The Supreme Court of Puerto Rico and the Puerto Rico intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Puerto Rico law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Puerto Rico would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

Puerto Rico products liability law requires product identification. *See Rivera Santana v. Superior Packaging Inc.*, 132 D.P.R. 115, 125–26 (P.R. 1992) (explaining that "[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being") (quotations omitted). However, Puerto Rico does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. And, the Court is unaware of any Puerto Rico caselaw indicating that those claims would be construed as products liability claims. The Supreme Court of Puerto Rico could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Puerto Rico law. As a result, the Court must predict whether the Supreme Court of Puerto Rico would find that Defendants owe a duty to Plaintiffs.

Under Puerto Rico law, a duty of care may arise: "(1) by statute or regulation; (2) 'as the result of a special relationship between the parties that has arisen through custom; or (3) as the result of a traditionally recognized duty of care particular to the situation.' " *Baum-Holland v. Hilton El Con Mgmt., LLC*, 964 F.3d 77(1st Cir. 2020) (quoting *De Jesús-Adorno v. Browning Ferris Indus. of P.R., Inc.*, 160 F.3d 839, 842 (1st Cir. 1998)). There is no Puerto Rico statute or regulation that imposes a duty on brand-name manufacturers to generic consumers. Nor is there a "special relationship between the parties" from which a duty of care may be recognized; in fact, there is no relationship between brand-name manufacturers and generic consumers. Further, there exists no "traditionally recognized duty of care" requiring a brand-name manufacturer to go beyond ensuring the safety of its own product. Thus, the Court predicts that the Supreme Court of Puerto Rico would not recognize a duty owed by Defendants to Plaintiffs triggering liability under Puerto Rico law.

In sum, the Court predicts that the Supreme Court of Puerto Rico would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Puerto Rico law.

28. Rhode Island

The Rhode Island Supreme Court and the Rhode Island intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Rhode Island law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Rhode Island Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

***33** Rhode Island products liability law requires product identification. *See Clift v. Vose Hardware, Inc.*, 848 A.2d 1130, 1132 (R.I. 2004) (per curiam) (noting that "it is axiomatic that a plaintiff must prove that the proximate cause of his or her injuries was the defendant's product") (quotation omitted). However, Rhode Island does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Rhode Island caselaw indicating that those claims would be construed as products liability claims. The Rhode Island Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Rhode Island law. As a result, the Court must predict whether the Rhode Island Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty exists, Rhode Island courts consider "all relevant factors, including the relationship between the parties, the scope and burden of the obligation to be imposed upon the defendant, [and] public policy considerations," *Volpe v. Gallagher*, 821 A.2d 699, 705 (R.I. 2003). Courts also consider "the foreseeability of harm to the plaintiff." *Banks v. Bowen's Landing Corp.*, 522 A.2d 1222, 1225 (R.I. 1987).

After weighing these factors, the Court predicts that the Rhode Island Supreme Court would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. There is no relationship between brand-name drug manufacturers and generic consumers, and the burden to Defendants and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name competitors liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (reasoning that "extending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks"); *McNair*, 818 S.E.2d at 866 (explaining that "[i]f brand manufacturers become liable for injuries allegedly caused by generic drugs, significant litigation costs would be added to the price of new drugs to the disadvantage of consumers" and "the increase in litigation ... could stifle the development of new drugs"). Additionally, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865).

In sum, the Court predicts that the Rhode Island Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Rhode Island law.

29. South Carolina

The South Carolina Supreme Court and the South Carolina intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under South Carolina law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the South Carolina Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

The federal District of South Carolina has predicted that the South Carolina Supreme Court would hold that South Carolina law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Fisher v. Pelstring,* No. 4:09-CV-00252-TLW, 2010 WL 2998474, at *10 (D.S.C. July 28, 2010). In making this predication, the court relied on the reasoning of analogous federal court decisions that this Court has already deemed persuasive. *See id.* at *4-5 (citing *Foster*, 29 F.3d at 167-71 and *Couick*, 691 F. Supp.2d at 645-56). The court also cited to several instructive decisions within the state of South Carolina, which "indicated that the courts of South Carolina would apparently not allow a tort recovery against a defendant for injuries caused by a product manufactured, distributed, and sold by a third party to which the plaintiff has no connection." *Id.* at *6; *see also Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004, 1006-07 (D.S.C. 1981) (applying South Carolina law and noting that "[t]he defendant manufacturer must be identified with the specific instrumentality that allegedly caused the injury" and that "[p]roof connecting the defendant with the instrumentality of the alleged defect is necessary regardless of the theory upon which plaintiff relies"); *Baughman v. Gen. Motors Corp.*, 627 F. Supp. 871, 878 (D.S.C. 1985) (holding that "[b]ecause plaintiff cannot show that the defendant exercised dominion over the allegedly defective [product], defendant may not be held liable under any tort theory"). Thus, because the plaintiffs could not establish that the brand-name manufacturer defendants manufactured or sold the products allegedly responsible for their injuries, the court held that the plaintiffs' claims, whether based in theories of strict liability or negligence, failed for lack of product identification and a duty. *Fisher*, 2010 WL 2998474, at *8.

***34** While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Fisher* to be "reliable data tending convincingly to show" whether the South Carolina Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the South Carolina Supreme Court would hold that Plaintiffs' claims fail for lack of a duty triggering liability under South Carolina law.

30. South Dakota

The South Dakota Supreme Court and the South Dakota intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under South Dakota law. Therefore, the Court must

make a prediction using all "reliable data tending convincingly to show" whether the South Dakota Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

South Dakota products liability law requires product identification. *See Bradley v. Firestone Tire & Rubber Co.*, 590 F. Supp. 1177, 1179 (D.S.D. 1984) (explaining that "[i]t is a fundamental principle that a plaintiff must prove, as an essential element of his case, that the defendant manufacturer actually made the particular product in question"). However, South Dakota does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any South Dakota caselaw indicating that those claims would be construed as products liability claims. The South Dakota Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under South Dakota law. As a result, the Court must predict whether the South Dakota Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty exists, South Dakota courts look to "whether a 'relationship exists between the parties such that the law will impose upon the defendant a legal observation of reasonable conduct for the benefit of the plaintiff.' " *Zerfas v. AMCO Ins. Co.*, 873 N.W.2d 65, 69 (S.D. 2015) (quoting *First Am. Bank & Tr., N.A. v. Farmers State Bank*, 756 N.W.2d 19, 26 (S.D. 2008). Additionally, foreseeability of injury to the plaintiff and public policy play "major" roles in identifying a legal duty. *Englund v. Vital*, 838 N.W.2d 621, 632 (S.D. 2013) (Konenkamp, J., concurring) (citing *Kirlin v. Halverson*, 758 N.W.2d 436, 453 (S.D. 2008)).

The Court predicts that the South Dakota Supreme Court would hold that a generic consumer's negligence claims against a brand-name manufacturer fail for lack of a duty triggering liability. As previously discussed, the Court finds there to be a complete absence of a relationship between a generic consumer and a brand-name manufacturer. Further, generic consumers' injuries are not the foreseeable result of brand-name manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). Additionally, as other courts have concluded, many public policy considerations weigh against holding brand-name competitors liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (finding that "extending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks") (citing Schwartz et al. at 1870–72); *McNair*, 818 S.E.2d at 866 (explaining that "[i]f brand manufacturers become liable for injuries allegedly caused by generic drugs, significant litigation costs would be added to the price of new drugs to the disadvantage of consumers" and "the increase in litigation ... could stifle the development of new drugs").

***35** In sum, the Court predicts that the South Dakota Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under South Dakota law.

31. Utah

The Utah Supreme Court and the Utah intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Utah law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Utah Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Utah products liability law requires product identification. *Bylsma v. R.C. Willey*, 416 P.3d 595, 604 (Utah 2017) (explaining that liability may only be imposed on parties "involved in the product's chain of distribution"). However, Utah does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Utah caselaw indicating that those claims would be construed as products liability claims. The Utah Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Utah law. As a result, the Court must predict whether the Utah Supreme Court would find that Defendants owe a duty to Plaintiffs.

In determining whether a duty exists, Utah courts consider: "(1) the extent that the manufacturer could foresee that its actions would cause harm; (2) the likelihood of injury; (3) the magnitude of the burden of guarding against it; and (4) the consequences of placing the burden on the defendant." *Slisze v. Stanley-Bostitch*, 979 P.2d 317, 320 (Utah 1999). After weighing these factors, the Court predicts that the Utah Supreme Court would follow the majority view and hold that brand-name manufacturers do not owe a duty to generic consumers. As previously discussed, generic consumers' injuries are not the foreseeable result of brand-name manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). Additionally, as other courts have concluded, many public policy considerations weigh against holding brand-name competitors liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (finding that "extending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks"); *McNair*, 818 S.E.2d at 866 (explaining that "[i]f brand manufacturers become liable for injuries allegedly caused by generic drugs, significant litigation costs would be added to the price of new drugs to the disadvantage of consumers" and "the increase in litigation ... could stifle the development of new drugs").

In sum, the Court predicts that the Utah Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Utah law. [16]

32. Vermont

***36** The Vermont Supreme Court and the Vermont intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Vermont law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Vermont Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Vermont products liability law requires product identification. *Farnham v. Bombardier, Inc.*, 161 Vt. 619, 640 A.2d 47, 48 (1994) (holding that "a plaintiff must show that the defendant's product... caused injury to the consumer because of its defective design"). As for Plaintiffs' negligence-based claims, the District of Vermont has predicted that the Vermont Supreme Court would recognize a duty owed by brand-name manufacturers to generic consumers. *See Kellogg*, 762 F. Supp. 2d at 709. In reaching this conclusion, the court began by noting that "[n]either the Vermont courts nor the Vermont legislature have collapsed negligence actions into strict liability actions where products are involved." *Id.* at 704. Thus, the court found the plaintiff's negligence-based claims were distinct from products liability claims and proceeded to determine whether a duty was owed by brand-name manufacturers to generic consumers. The court explained that, in determining whether a duty is owed, Vermont courts primarily consider the foreseeability of the risk, but also look to "the relationship of the parties, the nature of the risk, and the public interest at stake." *Id.* at 705 (quoting *Hamill v. Pawtucket Mut. Ins. Co.*, 179 Vt. 250, 892 A.2d 226, 228 (2005)); *see also Langle v. Kurkul*, 146 Vt. 513, 510 A.2d 1301, 1305 (1986). The court held that because

> [a] pharmacist is required by law to substitute the lowest priced generic equivalent when filling a prescription for a drug, unless otherwise instructed by the prescriber ... it is routine ... and entirely foreseeable, that a physician will prescribe a drug in reliance upon information disseminated by the brand name manufacturer, and that the patient with receive and ingest a generic equivalent.

Kellogg, 762 F. Supp. 2d at 705-06. The court further held imposing a duty would not be unfair to brand-manufacturers. *Id.* at 706.

The Court agrees with the District of Vermont insofar as the Court concludes that the Vermont Supreme Court could view Plaintiffs' negligence-based claims as distinct from products liability claims under Vermont law. However, the Court disagrees with the District of Vermont's reasoning and conclusion regarding whether the Vermont Supreme Court would recognize a

duty owed by brand-name manufacturers to generic consumers. Generic consumers' injuries are "not the foreseeable result of the brand manufacturers' conduct, but of the [Vermont and federal] laws over which the brand manufacturers have no control," and to use "these laws as the basis of supplying the duty element for tort liability stretches foreseeability too far." *In re Darvocet*, 756 F.3d at 944; *see also* Schwartz et al. at 1865. Additionally, the District of Vermont failed to account for the "grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher brand name drugs and fewer innovative drugs" and the complete absence of any relationship between brand-name manufacturers and generic consumers. *In re Darvocet*, 756 F.3d at 944; *see also McNair*, 818 S.E.2d at 864 n.11 (finding the reasoning in *Kellogg* unpersuasive and declining to recognize a duty owed by brand-manufacturers to generic consumers).

***37** In sum, the Court predicts that the Vermont Supreme Court would hold that Plaintiffs' claims fail either for lack of product identification and a duty giving rise to liability under Vermont law.

33. Virginia

The Supreme Court of Virginia and the Virginia intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Virginia law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Virginia would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

The Northern District of Illinois has predicted that the Supreme Court of Virginia would hold that Virginia law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Colas v. Abbvie, Inc.*, No. 14 C 1452, 2014 WL 2699756, at *2 (N.D. Ill. June 13, 2014). In making this determination, the court noted that, under Virginia law, only "one who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel." *Id.* (quoting Restatement (Second) of Torts § 388 (Am. Law Inst. 1965)); *see also Featherall v. Firestone Tire & Rubber Co.*, 219 Va. 949, 252 S.E.2d 358, 366 (1979) (adopting § 388 and stating that "[t]he duty to warn stems from the view that the manufacturer should have superior knowledge of his product"). Because the brand-name manufacturer defendant was not the supplier of the drug that the plaintiff ingested, the plaintiff's negligent failure to warn claim failed. *Colas*, 2014 WL 2699756, at *2; *see also Baker v. Poolservice Co.*, 272 Va. 677, 636 S.E.2d 360, 365 (2006) (stating that the plaintiff's "reliance on *Featherall* and § 388 of the Restatement (Second) of Torts to argue [that a spa repair service] owed a duty to warn [was] ... misplaced" because the repair service "was not the manufacturer of the spa"). The court held that "the Virginia failure to warn decisions, and the weight of authority from other jurisdictions, suggests that the Virginia Supreme Court would not recognize such duty." *Colas*, 2014 WL 2699756, at *2.

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Colas* to be "reliable data tending convincingly to show" whether the Supreme Court of Virginia would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Supreme Court of Virginia would hold that Plaintiffs' claims fail for lack of a duty triggering liability under Virginia law.

34. Wisconsin

The Wisconsin Supreme Court and the Wisconsin intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Wisconsin law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Wisconsin Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

***38** Wisconsin products liability law requires product identification. *See Green v. Smith & Nephew AHP, Inc.*, 245 Wis.2d 772, 629 N.W.2d 727, 746 (2001) (holding that "strict products liability holds that manufacturer responsible for injuries caused by that product"). However, Wisconsin does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Wisconsin caselaw indicating that those claims would be construed as products liability claims. The Wisconsin Supreme Court could consider Plaintiffs' negligence-based claims as distinct from

products liability claims under Wisconsin law. As a result, the Court must predict whether the Wisconsin Supreme Court would find that Defendants owe a duty to Plaintiffs.

A Wisconsin appellate court has made clear that "a manufacturer only owes a duty to warn regarding its own products, not products it did not manufacture, sell, or otherwise place in the stream of commerce." *Schreiner v. Wieser Concrete Prods. Inc.*, 294 Wis.2d 832, 720 N.W.2d 525, 531 (Wis. Ct. App. 2006). Additionally, when determining the existence of a duty, Wisconsin courts look to whether "it was foreseeable that the defendant's act or omission could harm or injure another person." *Morden v. Cont'l AG*, 235 Wis.2d 325, 611 N.W.2d 659, 674 (2000). As discussed, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). Thus, given the appellate court's holding in *Schreiner* and the lack of foreseeability of generic consumers' injuries, the Court predicts that the Wisconsin Supreme Court would not impose a duty on brand-name drug manufacturers to generic consumers.

In sum, the Court predicts that the Wisconsin Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Wisconsin law.

35. Wyoming

The Wyoming Supreme Court and the Wyoming intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Wyoming law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Wyoming Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Wyoming products liability law requires product identification. *See Ogle v. Caterpillar Tractor Co.*, 716 P.2d 334, 342 (Wyo. 1986) (adopting the Restatement (Second) Torts § 402A, which explains that "[o]ne who sells any product ... is subject to liability for physical harm thereby caused if ... the seller is engaged in the business of selling such a product"). However, Wyoming does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Wyoming caselaw indicating that those claims would be construed as products liability claims. The Wyoming Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims. As a result, the Court must predict whether the Wyoming Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty is owed, Wyoming courts look to:

> (1) the foreseeability of harm to the plaintiff, (2) the closeness of the connection between the defendant's conduct and the injury suffered, (3) the degree of certainty that the plaintiff suffered injury, (4) the moral blame attached to the defendant's conduct, (5) the policy of preventing future harm, (6) the extent of the burden upon the defendant, (7) the consequences to the community and the court system, and (8) the availability, cost and prevalence of insurance for the risk involved.

***39** *Gates v. Richardson*, 719 P.2d 193, 196 (Wyo. 1986).

After weighing these factors, the Court predicts that the Wyoming Supreme Court would follow the majority view and hold that brand-name drug manufacturers do not owe a duty to generic consumers. First, generic consumers' injuries are not the foreseeable result of brand-name manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944, Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). To impose a duty under Wyoming law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171.

Further, the Court finds that the connection between brand-name manufacturers' conduct and generic consumers injuries is attenuated, given the absence of a relationship between the them. And the burden to brand-name manufacturers and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name manufacturers liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (finding that "extending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks"); *McNair*, 818 S.E.2d at 866 (explaining that "[i]f brand manufacturers become liable for injuries allegedly caused by generic drugs, significant litigation costs would be added to the price of new drugs to the disadvantage of consumers" and "the increase in litigation ... could stifle the development of new drugs").

In sum, the Court predicts that the Wyoming Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Wyoming law.

All Citations

--- F.Supp.3d ----, 2020 WL 7866660

Footnotes

1 A court must accept a plaintiff's factual allegations as true at the motion–to–dismiss stage. *West v. Warden*, 869 F.3d 1289, 1296 (11th Cir. 2017) ("When considering a motion to dismiss, we accept as true the facts as set forth in the complaint and draw all reasonable inferences in the plaintiff's favor." (quotation marks omitted)). Plaintiffs have set forth their factual allegations in three "master" complaints: the Master Personal Injury Complaint ("MPIC"), the Consolidated Consumer Class Action Complaint ("CCCAC"), and the Consolidated Third Party Payor Class Complaint ("CTPPCC") (collectively "Master Complaints"). DE 887, 888, 889.

2 Unless noted otherwise, all page number references herein are to the page numbers generated by CM/ECF in the header of each document.

3 "Individual complaints" are personal injury complaints that plaintiffs to this litigation have filed in their individual cases. "Short Form Complaints" are complaints that plaintiffs to this litigation have filed in their individual cases using the form attached to the MPIC. *See* DE 887-1.

4 Defendants argue that lack of personal jurisdiction is an independent ground for dismissal of all of Plaintiffs' claims in all jurisdictions. DE 1585 at 14 n.3. However, they focus on the lack of personal jurisdiction in California and Massachusetts because they argue that those are the only states that recognize Plaintiffs' theory of liability. *Id.*

5 Defendants acknowledged in the Motion to Dismiss that California and Massachusetts have recognized Plaintiffs' theory of liability [DE 1585 at 6], and Plaintiffs acknowledged in their Opposition that their theory of liability is not viable under the laws of Alabama, Iowa, West Virginia, or Florida [DE 1973 at 11]. Therefore, the Court did not require supplemental briefing on those states. In their supplemental briefing, Plaintiffs apprised the Court that they are not pursuing claims under their theory of liability in the following additional eleven jurisdictions: Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, New Jersey, Ohio, Tennessee, Texas, and Washington. DE 2307 at 25.

6 The 35 jurisdictions are: Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Wisconsin, and Wyoming.

7 *See also Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 616 & n.3 (5th Cir. 2014) (finding no liability under Louisiana law of a brand-name manufacturer for injuries caused by ingestion of a generic drug and observing that "[o]ur decision is consistent with other circuit decisions that have held (under the laws of several different states) that brand-name

manufacturers are not liable for injuries caused by a plaintiffs ingestion of generic products"); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 681–82 (5th Cir. 2014) (finding no liability under Texas Law); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476–78 (5th Cir. 2014) (finding no liability under Mississippi and Texas law); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1281–86 (10th Cir. 2013) (finding no liability under Florida law); *Strayhorn v. Wyeth Pharms.*, Inc., 737 F.3d 378, 401–06 (6th Cir. 2013) (finding no liability under Tennessee law); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1093 (8th Cir. 2013) (finding no liability under Arkansas law); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183 (5th Cir. 2012) (per curiam) (finding no liability under Louisiana law); *Smith*, 657 F.3d at 423–24 (finding no liability under Kentucky law); *Foster v. Am. Home Prod. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994) (finding no liability under Maryland law).

8 *See Rafferty*, 92 N.E.3d at 1219 (recognizing a duty to refrain from acting recklessly under Massachusetts law); *T.H. v. Novartis*, 226 Cal.Rptr.3d 336, 407 P.3d at 47 (recognizing a duty of ordinary care under California law); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676 (Ala. 2014) (recognizing a duty of ordinary care under Alabama law), *superseded by statute,* Ala. Code § 6-5-530(a); *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 714 (N.D. Ill. 2014) (recognizing a duty of ordinary care under Illinois law), *rev'd on other grounds sub nom. Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803 (7th Cir. 2018); *Garner v. Johnson & Johnson, Janssen Rsch. & Dev. LLC*, No. 116-CV-01494, 2017 WL 6945335, at *7 (C.D. Ill. Sept. 6, 2017) (recognizing a duty of ordinary care under Illinois law); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010) (recognizing a duty of ordinary care under Vermont law).

9 As Plaintiffs have failed to plead a prima facie case of personal jurisdiction and have not moved for jurisdictional discovery, their request for jurisdictional discovery within their Opposition is denied at this stage. *See Butler v. Sukhoi Co.*, 579 F.3d 1307, 1313–15 (11th Cir. 2009) (concluding that a complaint failed to plead a prima facie case of subject matter jurisdiction and stating that, "[i]nasmuch as the complaint was insufficient as a matter of law to establish a prima face case that the district court had jurisdiction, the district court abused its discretion in allowing the case to proceed and granting discovery on the jurisdictional issue"); *Hinkle v. Cirrus Design Corp.*, 775 F. App'x 545, 550 (11th Cir. 2019) (upholding the district court's decision to deny "requests" for jurisdictional discovery when the party buried such requests in its briefs instead of presenting them in a motion).

10 The Eastern District of Kentucky has twice predicted that the Arizona Supreme Court would hold that Arizona law does not support imposing liability on a brand-name defendant for a generic manufacturer's product due to lack of product identification. *See In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 2012 WL 3842045, at *7–8 (E.D. Ky. Sept. 5, 2012) (holding that the plaintiffs' claims failed for lack of product identification), *aff'd on other grounds*, 756 F.3d 917 (6th Cir. 2014); *In re Darvocet, Darvon & Propoxyphene Product Liability Litigation*, 2012 WL 4831632, at *2–3 (E.D. Ky. Oct. 10, 2012) (same), *aff'd on other grounds*, 756 F.3d 917 (6th Cir. 2014). However, the court cited to no Arizona caselaw or statute in support of its prediction, and, because no Arizona plaintiff appealed, the Sixth Circuit did not analyze the claims under Arizona law as it did for twenty-two other states. Thus, while the Court takes note of these cases, the Court does not end its analysis of Arizona law there.

11 The Sixth Circuit also predicted that the Arkansas Supreme Court would reject this theory of liability, relying upon the Eighth Circuit's reasoning in *Bell*. *See In re Darvocet,* 756 F.3d at 941.

12 The Sixth Circuit and the federal District Court of Maryland also predicted that the Maryland Court of Appeals would reject this theory of liability, relying upon the Fourth Circuit's reasoning in *Foster*. *See In re Darvocet*, 756 F.3d at 946; *Gross v. Pfizer, Inc.*, No. 10-CV-00110-AW, 2010 WL 4485774, at *2–3 (D. Md. Nov. 9, 2010).

13 The Sixth Circuit and two federal Mississippi federal district courts have also predicted that the Supreme Court of Mississippi would reject this theory of liability, relying upon the Fifth Circuit's reasoning in *Lashley*. *See In re Darvocet,* 756 F.3d at 947–48; *Truddle v. Wyeth, LLC*, No. 2:11-CV-00207-GHD, 2015 WL 160696, at *4 (N.D. Miss. Jan. 12, 2015); *Chatman v. Pfizer, Inc.*, No. 5:11-CV-69 DCB MTP, 2014 WL 4546042, at *3 (S.D. Miss. Sept. 11, 2014).

14 The Sixth Circuit, the District of Massachusetts, and the Southern District of New York also predicted that the New York Court of Appeals would reject this theory of liability, relying upon the reasoning in *Goldych* and *Weese*. *See In re Darvocet*, 756 F.3d at 949; *Coleson*, 251 F. Supp. 3d at 721–22; *In re Zofran*, 261 F. Supp. 3d at 78–79.

15 The Sixth Circuit relied upon the reasoning in *Couick* in making its prediction that the North Carolina Supreme Court would reject this theory of liability. *See In re Darvocet*, 756 F.3d at 949.

16 A Utah state trial court held that brand-name manufacturers owe no duty to generic drug consumers, relying heavily upon the Fourth Circuit's decision in *Foster*. *See Beutella v. A.H. Robins Co.*, No. 980502372, 2001 WL 35669202, at

*3 (Utah Dist. Ct. Dec. 10, 2001). However, "in light of the huge caseloads carried by the trial courts," the court opted not to draft a detailed ruling and did not analyze Utah law in any depth. *Id.* at *3 n.4. Thus, the Court does not find the decision particularly persuasive.

End of Document

2019 WL 6456186 (Idaho Dist.) (Trial Order)
Idaho District Court.
Fourth Judicial District
Ada County

Michelle STIRLING and Brandon Stirling, individually and as the natural parents of minor child B.S., Plaintiffs,
v.
NOVARTIS PHARMACEUTICALS CORPORATION, Alcami Carolinas Corporation fka Aaipharma Services Corp., Genus Lifesciences Inc. dba Lehigh Valley Technologies, Lannett Company, Inc., Impax Laboratories, Inc., St. Luke's Regional Medical Center, Ltd., Glen Lovelace, M.D., Defendants.

No. CV01-18-4880.
September 25, 2019.

Memorandum Decision Re: Novartis Pharmaceuticals Motion to Dismiss

Richard D. Greenwood, Judge.

I. INTRODUCTION

***1** This matter is before the Court on the Motion to Dismiss filed by Defendant Novartis Pharmaceuticals Corporation ("Novartis"). Plaintiffs' Amended Complaint set out six causes of action against Novartis: (1) Count One—Negligent Failure to Warn; (2) Count Two—Fraud; (3) Count Three—Negligence Per Se; (4) Count Four—Breach of Implied Warranty of Merchantability; (5) Count Seven—intentional infliction of emotional distress ("IIED"); and (6) Count Eight—negligent infliction of emotional distress ("NIED"). Novartis requested the Court dismiss under I.R.C.P. 12(b)(2) for lack of personal jurisdiction and I.R.C.P. 12(b)(6) for failure of the Amended Complaint to state a claim for which relief can be granted. At the hearing Court on September 4, 2019 the Court declined to rule on the merits of the motion to dismiss for lack of jurisdiction pending Novartis responses to Plaintiffs' discovery directed to the jurisdictional facts. The Court took the 12(b)(6) portion of the motion under advisement.

Because this is a motion to dismiss, all facts are derived from the Amended Complaint. The Court announced at the hearing that it would not convert the motion into a motion for summary judgment. [1] Consequently, the Court will not consider any additional evidentiary materials filed by the parties when reaching the decision on the Rule 12(b)(6) motion. *See Paslay v. A&B Irrigation Dist.*, 162 Idaho 866, 870, 406 P.3d 878, 882 (2017) ("[A] court can dismiss an action under Rule 12(b)(6) if it considers only the complaint, despite whether a party has submitted additional materials to the record.").

II. FACTS AS ALLEGED BY PLAINTIFFS

The facts alleged as concerns Defendant are summarized here. Other facts contained in the Amended Complaint pertaining to other Defendants not germane to the question under consideration are omitted.

Defendant Novartis is a pharmaceutical company that owned [2] the New Drug Application ("NDA") for the brand-name drug Brethine from sometime before until December 2001. [3] Brethine was originally developed by Draco, a Swedish company, and released for use as a bronchodilator to treat asthma. Terbutaline sulfate is the generic form of Brethine. In 1974, the FDA approved terbutaline sulfate as a treatment for asthma in the United States. In its capacity as the owner of the Brethine NDA, Novartis developed, manufactured, packaged, labeled, marketed and distributed Brethine until around December 2001 when it

sold the rights to the Brethine NDA to Alcami Carolinas Corporation. Plaintiffs make no allegation that Novartis manufactured the drug taken by Plaintiff Michelle Stirling ("Michelle"). [4] The Amended Complaint does not allege the name of the actual manufacturer of the drug ingested by Michelle. It is clear, however, that the manufacturer was not Novartis.

***2** In late October 2007 Michelle was approximately twenty-five (25) weeks pregnant with her now ten-year-old son, B.S., when she began experiencing pre-mature labor contractions. She was prescribed an injection of the generic drug terbutaline sulfate as a tocolytic - a drug to suppress premature labor in pregnant women. Michelle continued the use of the drug in pill form for 90 consecutive days from the original injection on XX/XX/2007 into XX/XX/2008. B.S. was born on XX/XX/2008. At birth B.S. did not have any objective manifestations that indicated he had any cognitive or neuropsychiatric impairments or disorders but was eventually diagnosed with and treated for cognitive and personality disorders. These cognitive and personality disorders were caused by the terbutaline sulfate ingested by Michelle during her pregnancy. Michelle and her husband Brandon suffered damages, including emotional distress, as a result of the injury to B.S.

In the Amended Complaint, Plaintiffs include incongruous factual allegations that the use of Brethine and the generic terbutaline sulfate for tocolytic was both on and off-label. [5] "On-label use" is when a drug or medical device is used in a manner approved by the FDA, including treatment for use on identified and specific conditions and diseases. In contrast, "off-label" usage is the "use of a device for some other purpose than that for which it has been approved by the FDA." *See Buckman Co. v. Plaintiff's Legal Comm.,* 531 U.S. 341, 350, 121 S.Ct. 1012, 1018, 148 L.Ed.2d 854 (2001). The Supreme Court's observations regarding medical devices applies equally to drugs. James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions,* 53 Food & Drug L.J. 71 (1998). The Court will accept that the use of the drug as a tocolytic was both on and off label because this is a 12(b)(6) motion.

III. STATUTORY SCHEME RELATED TO PHARMACEUTICAL DRUG LABELING

***3** The Food, Drug, and Cosmetic Act (FDCA; 21 U.S.C. § 301 *et seq*.) prohibits the marketing of a new brand-name drug unless the manufacturer has submitted a new drug application ("NDA") and the Food and Drug Administration ("FDA") has approved the drug as safe and effective for its intended use. 21 U.S.C. § 355(a). The NDA must include an exemplar of the drug's proposed label (21 U.S.C. § 355(b)(1)(F)) describing the drug's indications and usage, contraindications, warnings and precautions, and adverse reactions. 21 C.F.R. § 201.56(e)(1).

The United States Supreme Court has outlined general drug labeling requirements, stating:

> Under the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act, 76 Stat. 780, 21 U.S.C. § 301 *et seq*., a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate. See, *e.g.*, 21 U.S.C. §§ 355(b)(1), (d); *Wyeth v. Levine*, 555 U.S. 555, 567, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009). Meeting those requirements involves costly and lengthy clinical testing. §§ 355(b)(1)(A), (d); *see also* D. Beers, Generic and Innovator Drugs: A Guide to FDA Approval Requirements § 2.02[A] (7th ed. 2008).
>
> Originally, the same rules applied to all drugs. In 1984, however, Congress passed the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, commonly called the Hatch-Waxman Amendments. Under this law, "generic drugs" can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA. 21 U.S.C. § 355(j)(2)(A). As we use it here, "generic drug" refers to a drug designed to be a copy of a reference listed drug (typically a brand-name drug), and thus identical in active ingredients, safety, and efficacy. See, *e.g., United States v. Generix Drug Corp.*, 460 U.S. 453, 454-455, 103 S.Ct. 1298, 75 L.Ed.2d 198 (1983); 21 CFR § 314.3(b) (2006) (defining "reference listed drug"). This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug. A generic drug application must also "show that the [safety and efficacy] labeling proposed… is the same as the

> labeling approved for the [brand-name] drug." § 355(j)(2)(A)(v); see also § 355(j)(4)(G); Beers §§ 3.01, 3.03[A].

PLIVA, Inc. v. Mensing, 564 U.S. 604, 612-13, 131 S. Ct. 2567, 2574, 180 L. Ed. 2d 580 (2011) (relevant footnotes included in body of text).

> The FDA has created procedures by which manufacturers can make changes to a drug's approved labeling or other changes to an approved application. Drug manufacturers may submit either "Prior Approval Supplements," which require FDA approval before the proposed change may be implemented, or "Changes Being Effected" ("CBE") Supplements, under which the proposed change may be implemented before the FDA has acted on the supplemental application. 21 C.F.R. § 314.70(b), (c). While most changes to a drug's approved labeling must be requested through a Prior Approval Supplement, manufacturers may "add or strengthen a contraindication, warning, precaution, or adverse reaction" through a CBE supplement. *See* §§ 314.70(b)(1)(i), § 314.70(c)(6)(iii)(A).
>
> Under current regulations, brand-name and generic manufacturers have different labeling responsibilities, even though both are authorized to use the label supplement procedures. 21 C.F.R. § 314.97. *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 923 (6th Cir. 2014).

***4** Thus, under the regulatory scheme, a brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label, (See, *e.g.*, 21 U.S.C. §§ 355(b)(1), (d); *Wyeth, supra*, at 570-571, 129 S.Ct. 1187), whereas a generic manufacturer is responsible for ensuring that its warning label is the same as the brand name label. *See, e.g.*, § 355G)(2)(A)(v); § 355Q(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7).

IV. APPLICABLE LAW

Pursuant to Idaho Rule of Civil Procedure 12(b)(6), a claim is properly dismissed when the complaint "[fails] to state a claim upon which relief can be granted." When reviewing a motion to dismiss for failure to state a claim, a court looks only to the pleadings and views all inferences in favor of the non-moving party. *Young v. City of Ketchum*, 137 Idaho 102, 104 (2002). Under this standard, the Court will determine whether a plaintiff has stated a claim for relief "after viewing all facts and inferences from the record in favor of the non-moving party." *Taylor v. McNichols*, 149 Idaho 826, 832 (2010). "The issue is not whether the plaintiff will ultimately prevail, but whether the party is entitled to offer evidence to support the claims." *BHA Investments, Inc. v. State*, 138 Idaho 348, 350-51 (2003) (citing *Orthman v. Idaho Power Co.*, 126 Idaho 960, 962 (1995), *quoting Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). While the Court "assum es that all *factual* allegations in the complaint are true … [it] is not obligated to assume that a plaintiff's *legal conclusions* or *arguments* are also true." *Owsley v. Idaho Indus. Comm'n*, 141 Idaho 129, 136 (2005).

V. DISCUSSION

i. *Innovator Liability*

Novartis asserts that Plaintiffs' claims against Novartis are premised on this Court's recognition of "innovator liability."[6] Plaintiffs' Amended Complaint does not have a count labeled "innovator liability." Plaintiffs define innovator liability as a theory under which a brand-name drug manufacturer may be held liable for injuries caused by an individual's ingestion of the generic version of its drug. *See, Plaintiffs' Memorandum in Opposition to Novartis Motion to Dismiss*, p. 1, footnote 2. The logic that underlies this theory of liability is that a generic manufacturer of a drug has no ability to control the content of the label. It is the brand name manufacturer that must ensure that the warning label for the drug is accurate and adequate under

§ 505 of the Federal Food, Drug, and Cosmetic Act. *See, e.g. Rafferty v. Merck & Co., Inc.*, 479 Mass. 141, 92 N.E.3d 1205 (2018); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt.2010).

Plaintiffs acknowledge Idaho Courts have not recognized a cause of action for innovator liability, but argue Idaho courts have not considered the theory and this Court should allow Plaintiffs to raise a claim for innovator liability "because the theory is consistent with Idaho law, does not impose an undue burden upon brand-name manufacturers and promotes critical public policies." [7]

Novartis cites to contrary cases rejecting innovator liability. *See, e.g., McNair v. Johnson & Johnson*, 241 W. Va. 26, 818 S.E.2d 852 (2018); *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013). Novartis argues that "[l]ike the vast majority of states, Idaho does not recognize a cause of action based on an innovator liability theory." Novartis does not cite, and the Court could not find, any Idaho case so holding. It is more accurate to say that the Idaho appellate courts have not considered the question.

***5** A review of the allegations in count in Plaintiffs' Amended Complaint that pertain to Novartis reveals that all have a crucial fact in common. Novartis did not manufacture the drug that caused the injuries.

ii. *Count One - Negligent Failure to Warn*

A cause of action for common law negligence has four elements: "(1) a duty, recognized by law, requiring the defendant to conform to a certain standard of conduct; (2) a breach of that duty; (3) a causal connection between the defendant's conduct and the resulting injury; and (4) actual loss or damage. *Nation v. State, Dep't of Correction*, 144 Idaho 177, 189, 158 P.3d 953, 965 (2007) (quoting *O'Guin v. Bingham County*, 142 Idaho 49, 52, 122 P.3d 308, 311 (2005)). Count 1 of the Amended Complaint, albeit in a rather wordy fashion, sufficiently alleges these elements. The motion by Novartis essentially challenges whether a legal duty exists in the context of this case. [8] In other words, does Idaho law require the manufacturer of a product, in this case a drug, to warn the consumer of a similar product manufactured by another. The Court concludes it does not. A collection and succinct discussion of the cases and citation to the conflicting policy arguments is found in *In re Zofran (Ondansetron) Products Liab. Litig.*, 2018 WL 2317525 (D. Mass. May 21, 2018).

The Idaho Supreme Court in *Boots* outlined the basic rule for determining whether a duty will arise in a particular context, stating:

> In determining whether a duty will arise in a particular context, our Supreme Court has identified several factors to consider. The factors include the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved. Where the degree or result of harm is great, but preventing it is not difficult, a relatively low degree of foreseeability is required. Conversely, where the threatened injury is minor but the burden of preventing such injury is high, a higher degree of foreseeability may be required. We engage in a balancing of the harm only in those rare situations when we are called upon to extend a duty beyond the scope previously imposed or when a duty has not previously been recognized.

Boots ex rel. Boots v. Winters, 145 Idaho 389, 394, 179 P.3d 352, 357 (Ct. App. 2008) (internal citations removed).

It has long been the general law in Idaho that a company is not liable for the injuries caused by another company's products. *See e.g., Garrett v. Nobles*, 102 Idaho 369, 372, 630 P.2d 656, 659 (1981); *see e.g., Farmer v. Int'l Harvester Co.*, 97 Idaho 742, 746, 553 P.2d 1306, 1310 (1976).This Court finds persuasive the reasoning of the Supreme Court of Iowa in *Huck v. Wyeth, Inc.*, [9]:

***6** We are unwilling to make brand manufacturers the de facto insurers for competing generic manufacturers. (Deep pocket jurisprudence is law without principle.) It may well be foreseeable that competitors will mimic a product design or label. But, we decline Huck's invitation to step onto the slippery slope of imposing a form of innovator liability on manufacturers for harm caused by a competitor's product. Where would such liability stop? If a car seat manufacturer recognized as the industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor's seat that copied the design? Why not, under Huck's theory, if it is foreseeable others will copy the design?

In sum, we will not contort Iowa's tort law in order to create liability for brand manufacturers. The unfairness resulting from *Mensing* is best addressed by Congress or the FDA....

We will continue to apply the same long-standing causation rule … which required Huck to prove the defendant manufactured or supplied the product that caused her injury, and we decline to extend the duty of product manufacturers to those injured by use of a competitor's product. We will not impose liability on the brand defendants for injuries to those using only the competing generic formulation.

Huck, 850 N.W.2d at 380-81 (quotation marks and citations omitted). *See, also* Part III of *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612-14, (8th Cir. 2009), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 564 U.S. 604, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011), and *opinion vacated in part, reinstated in part*, 658 F.3d 867, (8th Cir. 2011).

iii. *Count Two -Fraud*

The discussion in *Huck* and *Mensing, supra*, applies as well to the fraud claims. In addition, a party claiming fraud must plead with particularity the factual circumstances constituting fraud *G & M Farms v. Funk Irr. Co.*, 119 Idaho 514, 518, 808 P.2d 851, 855 (1991). Those elements are (1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) his intent that it should be acted on by the person and in the manner reasonably contemplated; (6) the hearer's ignorance of its falsity; (7) his reliance on the truth; (8) his right to rely thereon; and (9) his consequent and proximate injury. *Id.* Missing from Plaintiff's complaint are is the particularity required to allege fraud. There are general statements that Novartis made false statements that its drugs were safe and effective, but nothing more. One cannot tell when the statements were made, by whom made, or what words were used. The general statement that Novartis promoted, marketed, and distributed Brethine and terbutaline sulfate as a safe and effective tocolytic is not sufficiently specific.

The Amended Complaint does not state a claim for fraud.

iv. *Count Three - Negligence Per Se*

Negligence per se is simply a subset of negligence. The standard of conduct is defined by a statue or regulation. Proving violation of the statute or regulation, proves the violation of the standard of care. Before it can apply, a plaintiff must show membership in the class of persons the regulation was intended to protect. In other words, that the duty defined by the statute or regulation extends to plaintiff. Here the issue is the same as with common law negligence. The regulations protect the consumers of the manufacturer's product. Absent an allegation that Michelle took a drug made by Novartis, the complaint does not state a cause of action.

A collection and succinct discussion of the cases and citation to the conflicting policy arguments is found in *In re Zofran (Ondansetron) Products Liab. Litig.*, 2018 WL 2317525 (D. Mass. May 21, 2018). Ultimately this Court concludes that the traditional notion that the manufacturer of a product cannot be held liable where its product did not cause the alleged harm.

v. *Count Four - Breach of Implied Warranty of Merchantability*

***7** In Idaho, strict products liability and negligent rendition of service are not mutually exclusive theories. *Chancier v. Am. Hardware Mut. Ins. Co.*, 109 Idaho 841, 846, 712 P.2d 542, 547 (1985). In Idaho, non-privity, breach of warranty claims against a manufacturer to recover for personal injuries caused by a defective product are treated as a strict liability claims. *Oats v. Nissan Motor Corp. in U.S.A.*, 126 Idaho 162, 172, 879 P.2d 1095, 1105 (1994). To prove such a claim, a plaintiff must show that (1) the manufacturer's product was defective; (2) the product was defective or unsafe when it left the manufacturer's control; and (3) the defect was a proximate cause of the plaintiff's injury. *Puckett v. Oakfabco, Inc.*, 132 Idaho 816, 821, 979 P.2d 1174, 1179 (1999); *Garrett v. Nobles*, 102 Idaho 369, 372, 630 P.2d 656, 659 (1981).

Once again, this Court will not deviate from traditional products liability law principles in order to extend the duty of brand manufacturers to those allegedly injured by a competitor's product. The reasoning of the Iowa Court in *Huck* is likewise applicable here. Even if one accepts that Brethine was a defective product when last produced by Novartis in December 2001, it was not the product that caused the injuries. Because Novartis did not manufacture the product that Michelle was given, there is no proximate cause, and no basis under which this Court can hold Novartis liable.

vi. *Count Seven - intentional infliction of emotional distress*

To prove intentional infliction of emotional distress, a plaintiff must prove (1) defendant's intentional or reckless conduct; (2) defendant's extreme and outrageous conduct; (3) a causal connection between the defendant's wrongful conduct and the plaintiff's emotional distress; and (4) severe emotional distress. *James v. City of Boise*, 160 Idaho 466, 484, 376 P.3d 33, 51 (2016). Count Seven in Plaintiffs' Amended Complaint does not allege any additional facts. Rather it incorporates earlier allegations and characterizes Defendant's conduct as extreme and outrageous. Assuming, without deciding, that this is a proper characterization of Novartis's conduct, there is lacking a factual allegation linking the conduct to any harm suffered by Plaintiffs. The alleged outrageous conduct is apparently either the failing to properly label Brethine or promoting Brethine as a tocolytic. Because Michelle was not given Brethine, there is no causal connection to be made.

vii. *Count Eight -negligent infliction of emotional distress* To prove negligent infliction of emotional distress, a plaintiff must prove (1) a legal duty recognized by law; (2) a breach of that duty; (3) a causal connection between the defendant's conduct and the plaintiff's injury; and (4) actual loss or damage. *Frogley v. Meridian Joint Sch. Dist. No. 2*, 155 Idaho 558, 569, 314 P.3d 613, 624 (2013). Again, the Amended Complaint incorporates earlier allegations and characterizes Defendant's conduct as a breach of Defendant's duty to exercise ordinary care to prevent harm to others. The alleged negligent conduct is apparently either the failing to properly label Brethine or promoting Brethine as a tocolytic. For the same reasons that the Amended Complaint fails to state a cause of action for negligence, it fails to state a claim for negligent infliction of emotional distress.

VI. PENDING JURISDICTIONAL QUESTION

As noted above, this Court declined to rule on the merits of the motion to dismiss for lack of jurisdiction pending discovery of the jurisdictional facts. The conclusion reached by the Court in this motion presents a procedural conundrum. If this Court has no jurisdiction, a still open question, this decision is essentially a void advisory opinion. But entering and order of dismissal moots the question of jurisdiction. Consequently, no Order dismissing this case will be entered unless and until there is a determination that this Court has jurisdiction over Novartis.

VII. CONCLUSION

***8** The Court concludes Plaintiff's Amended Complaint fails to state a claim against Novartis as to each count in which Novartis is named. That conclusion is preliminary pending determination of whether this Court has jurisdiction over Novartis. The order dismissing the case will be held in abeyance pending determination of jurisdiction.

DATED' Signed: 9/25/2019 08:44 AM

<<signature>>

Richard D. Greenwood, Senior District Judge

cc: All Counsel - emailed

Footnotes

1 If a party presents matters outside of the pleadings for consideration on a 12(b) motion, and the Court does not exclude the consideration of these materials, then the motion must be treated as though it were a motion for summary judgment under I.R.C.P. 56.

2 At places in the Amended Complaint, Plaintiffs refer to Novartis as the owner of the rights to the drug. At other places, Plaintiffs refer to Novartis as the "holder" of the right so the drug. There does not appear to be any legal distinction. The Court will simply use the term "owner" to encompass both.

3 The Amended Complaint does not allege a date Novartis acquired the rights to the drug, only the date it sold the rights to another company. Plaintiffs' brief refers to dates stated in the Novartis brief, but those statements are not facts to be considered as they are not set forth in the Amended Complaint.

4 Where the context requires individual Plaintiffs be identified, first names will be used. No disrespect is intended.

5 *See* Amended Complaint (emphasis added):

Paragraph 23: at no time during Alcami's ownership of the Brethine NDA, [2001-2007] including at the time it sold the rights to that NDA to Genus, did Alcami's label for Brethine contain any warning that use of the drug as a tocolytic posed a risk to fetal brain development, *even though the label allowed for administration for pre-term labor.*

Paragraph 24: at no time in 2007 or through February 18, 2008, when Genus owned the Brethine NDA, did Genus' label for Brethine contain any warning that use of the drug as a tocolytic posed a risk to fetal brain development, *even though the label allowed for administration for pre-term labor.*

Paragraph 25: At no time in late 2007 or early 2008 did the labels for these companies' respective terbutaline sulfate drugs contain any warning that use of the drug as a tocolytic posed a risk to fetal brain development, *even though the labels allowed for administration for pre-term labor.*

Paragraph 49: At all times relevant hereto, Defendants Novartis, Alcami, Genus, Lannett, Impax and Does I-XX (collectively the "Manufacturer Defendants") manufactured, marketed and distributed Brethine and/or its generic bioequivalent, terbutaline sulfate, with the intention that it be used in the *off-label manner as a tocolytic* by improperly promoting those drugs as safe and effective for that particular use.

Paragraph 50: the Manufacturer Defendants knew or reasonably should have known not only that Brethine and terbutaline sulfate *were not effective tocolytics*, but also that their use in such an *off-label manner* was not safe

Paragraph 56: Plaintiffs and their health care providers justifiably relied upon the Manufacturer Defendants' expertise and justifiably believed that… (4) not promote a drug for an **off-label use** that had been shown to be ineffective and dangerous.

Paragraph 63: At all times relevant hereto, the Brand-Name Manufacturer Defendants' Brethine drug products were misbranded under both the FDCA and the IFDCA in *that their labeling promoted the use of Brethine as a tocolytic* but failed to include any warning of the known risks to fetal brain development associated with such use.

Paragraph 78: At all times relevant hereto, the Brand-Name Manufacturer Defendants' *labeling* for Brethine was defective and deficient in that it *promoted and/or approved of the use of the drug as a tocolytic* ...

6 "Plaintiffs' Complaint… fails to state anyclaim against [Novartis] upon which relief can be granted because it relies solely on an "innovator liability" theory that is not a viable cause of action under Idaho Law." *Novartis Motion to Dismiss*. Pls' Response, pp. 5-6.

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8 Novartis makes much of the fact that there was a six-year gap between its alleged failure to act and the ingestion of the drug by Michelle. The time gap implicates the statute of limitations, not the existence of a duty to the Plaintiffs.

9 850 N.W.2d 353 (Iowa 2014) (rejecting the argument that brand manufacturers owe a duty to consumers of generic drugs).

2019 WL 1571834
Only the Westlaw citation is currently available.
United States District Court, D. Delaware.

Lamar A. TROWER, Plaintiff,
v.
JANSSEN PHARMACEUTICALS, INC., Defendant.

Civil Action No. 1:16-cv-00135-RGA
|
Signed 04/11/2019

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MEMORANDUM OPINION

ANDREWS, U.S. DISTRICT JUDGE

***1** Presently before me are Defendant's Motion for Summary Judgment (D.I. 155), Defendant's Motion to Preclude Expert Testimony of Brendan Carroll, M.D. (D.I. 158), and Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan (D.I. 161). The Parties have fully briefed the issues. (D.I. 156, 159, 162, 177, 178, 179, 187, 189, 191). I heard oral argument on March 7, 2019. For the reasons set out below, I will grant Defendant's Motion for Summary Judgment and I will dismiss Defendant's *Daubert* motions as moot.

I. BACKGROUND

Plaintiff suffers from a variety of serious mental illnesses. (D.I. 178 at 2). He has been diagnosed with ADHD, conduct disorder, oppositional defiant disorder, generalized anxiety disorder, major depressive disorder, PTSD, impulse control disorder, antisocial personality disorder, mild mental retardation, bipolar disorder, and schizophrenia. (*Id.*). Doctors have prescribed him Risperdal, [1] Haldol, Doxepin, Prozac, Depakote, Seroquel, Thorazine, Cylert, Clonidine, Elavil, Lexapro, Mellaril, Trazadone and Vistaril to treat these conditions. (*Id.*). Plaintiff was prescribed Risperdal from February 2011 through June 2011; October 2011 through February 2012; and August 2012 through August 2013. (*Id.*). Plaintiff allegedly discontinued use of Risperdal in early 2014. (*Id.* at 3).

Risperdal is FDA-approved for treatment of schizophrenia and bipolar disorder. (D.I. 156 at 5 n.2). Defendant is the manufacturer of brand name Risperdal. (D.I. 178 at 4). Risperidone is the generic name for Risperdal. (D.I. 156 at 5). Other drug manufacturers, such as Zydus Pharmaceuticals (USA), Inc., manufacture risperidone. (*Id.*).

Gynecomastia is a potential side effect of risperidone. (D.I. 178 at 5-7). Increased levels of prolactin may also be a side effect and is allegedly connected to an increased risk of gynecomastia. (D.I. 162 at 8). Gynecomastia is the enlargement of the male breast gland due to a hormonal imbalance. Prolactin is a hormone which enhances breast development and initiates lactation in the human (typically female) body.

Plaintiff filed this lawsuit on March 4, 2016. (D.I. 1). He pled seven claims against Defendant based on its marketing and sale of Risperdal: negligence (Count I), negligent misrepresentation (Count II), breach of warranty (Count III), breach of the implied warranty of merchantability (Count IV), breach of the implied warranty of fitness for a particular purpose (Count V), breach of express warranty (Count VI), and fraud by concealment (Count VII). (D.I. 29 at 4-7). He alleges that because of Defendant's conduct, he developed gynecomastia, breast pain, and discomfort, including hard nipples. (D.I. 156 at 6).

Defendant filed the present motions on October 12, 2018. It sought summary judgment on each count of the second amended complaint. (D.I. 29). In response to Defendant's summary judgment motion, Plaintiff voluntarily withdrew Counts III-VII. (D.I. 178 at 1 n. 1). Thus, the only Counts remaining are negligence and negligent misrepresentation.

II. LEGAL STANDARD

***2** "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460-61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations ..., admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence ... of a genuine dispute ...." Fed. R. Civ. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247-49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

III. DISCUSSION

A. Brand Name Liability for Plaintiff's Use of Generic Risperidone

The Parties do not dispute that Plaintiff's claim is based on his ingestion of generic risperidone. (D.I. 156 at 4-6; D.I. 178 at 12-17). Rather, they dispute whether, under Delaware law, a brand name manufacturer can be held liable, on a negligent failure to warn theory, for a plaintiff's injuries that result from consumption of a generic drug. (D.I. 156 at 10-11; D.I. 178 at 12-17). That question is an issue of first impression in Delaware.

Under federal law, brand name and generic drug manufacturers are not equally responsible for drug labeling. "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (citations omitted). This regulatory reality led the Supreme Court in *PLIVA* to find that federal law preempts state tort liability for a generic drug manufacturer's inadequate label. *Id.* at 623-24.

In her dissent, Justice Sotomayor noted that the *PLIVA* majority opinion "strips generic-drug consumers of compensation when they are injured by inadequate warnings." *Id.* at 643 (Sotomayor, J., dissenting). Plaintiff argues, "The problem is exacerbated because federal law encourages generic drug use and a majority of states have passed law[s] permitting pharmacists to substitute generic drugs without a patient's consent to save costs." (D.I. 178 at 15). Delaware is among the states with such a law. Del. Code Ann. tit. 24, § 2549A.

***3** Plaintiff proposes that the appropriate solution is to allow plaintiffs to maintain claims against brand name manufacturers for failure to warn, even when the plaintiffs ingested only the generic manufacturers' products. (D.I. 178 at 13). He argues this solution is desirable for two policy reasons: (1) "it ensures drug labels are consistent and consumers adequately warned, regardless of whether a generic or brand name drug is dispensed by a pharmacist," and (2) "imposing liability on brand name manufacturers better reflects what is actually at issue in failure to warn claims." (*Id.* at 15).

Beyond his policy-based argument, Plaintiff notes that some courts have allowed claims against brand name drug manufacturers in these circumstances. In 2014, the Alabama Supreme Court held that brand name manufacturers may be liable for harm caused by a generic manufacturer's product due to the brand name manufacturer's unique regulatory position. *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676-77 (Ala. 2014), *superseded by statute*, Ala. Code § 6-5-530(a) ("In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product."). Additionally, in 2010, a district court sitting in diversity held, "There is no reason, under Vermont law, to limit [a defendant's] duty of care to physicians by the pharmacist's choice of a generic bioequivalent drug to fill the physician's prescription" *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708-09 (D. Vt. 2010).

Defendant responds that Delaware law does not support imposing liability on defendants that did not make the allegedly harmful product. To state a claim in a products liability case, a plaintiff must plead facts that identify the allegedly defective product and the manufacturer of that product. *In re Benzene Litig*, 2007 WL 625054, at *6 (Del. Super. Ct. Feb. 26, 2007). "[G]eneric identification of a product is not enough to establish liability absent some other evidence that that generic product was the specific product of a defendant." *Lee v. A. C. & S., Inc.*, 1986 WL 15421, at *2 (Del. Super. Ct. Dec. 15, 1986). Moreover, at least one Delaware court has expressed hesitation when pressed to make changes to traditional tort law in the product liability space. *Nutt v. A.C. & S. Co.*, 517 A.2d 690, 694 (Del. Super. Ct. 1986) (choosing to defer to the legislature rather than judicially expand the scope of liability).

In response, Plaintiff cites to just one Delaware case, *Wilkerson v. Am. Honda Motor Co.*, 2008 WL 162522, at *2 (Del. Super. Ct. Jan. 17, 2008). In *Wilkerson*, the Superior Court held that a defendant may be liable for a plaintiff's asbestos exposure from a third-party product if it was reasonably foreseeable that use of defendant's product would result in use of the third-party product that would result in exposure to asbestos. *Id.* at *2. The court also held, "Any necessary warning must be tailored to the risks associated with the reasonably-anticipated use of the manufacturer's own product." *Id.* I understand *Wilkerson* to allow liability for a reasonably foreseeable harm that stems from use of a manufacturer's product, even when the actual vessel for the harm-causing agent was manufactured by a third party. I do not, however, agree with Plaintiff's conclusion that *Wilkerson* stands for the proposition that the question of liability starts and ends with whether a defendant owed a duty to a plaintiff. (D.I. 178 at 12 ("[T]he appropriate initial question is not whether Plaintiff ingested a drug manufactured by Defendant, but whether Defendant owed a duty to Plaintiff.")). Consistent with other Delaware cases, *Wilkerson* requires that defendant produced the product at the center of the dispute.

***4** Defendant further argues that the Third Circuit disfavors district courts creating new state law while sitting in diversity. When faced with "two competing yet sensible interpretations" of state law, the Third Circuit instructs that district courts should "opt for the interpretation that restricts liability, rather than expands it, until the [state's supreme court] decides differently." *Werwinskii v. Ford Motor Co.*, 286 F.3d 661, 680 (3d Cir. 2002); *see also Bruffett v. Warner Commc'ns, Inc.*, 692 F.2d 910, 920

(3d Cir. 1982) ("One of the authentic obligations of federalism at the judicial level requires that we permit the state courts to decide whether and to what extent they will follow the emerging law.").

I agree with Defendant. Delaware law does not support imposing liability on a brand name defendant for a generic manufacturer's product. I further agree with Defendant that, even if Delaware law provided some basis for imposing liability for failure to warn on brand name manufacturers, it would be imprudent for me to extend Delaware's law to that point while sitting in diversity. Accordingly, as it is undisputed that Defendant did not manufacture the pills that Plaintiff ingested, I will grant Defendant's motion for summary judgment.

B. Learned Intermediary Doctrine

Defendant also argues that it is entitled to summary judgment because Plaintiff cannot establish that an additional warning would have changed Plaintiff's physician's decision to prescribe Risperdal. (D.I. 156 at 12-13). Plaintiff's evidence of the inadequacy of the Risperdal label is identical to the evidence presented in a related case, *Green v. Janssen Pharms., Inc.*, Case No. 15-401-RGA (D. Del.), and is similarly insufficient to establish the Risperdal label was inadequate as a matter of law. Moreover, it is undisputed that none of Plaintiff's physicians were deposed for this litigation. (D.I. 156 at 12-13). Thus, as I explain more fully in my simultaneously-entered summary judgment opinion in the *Green* case, Plaintiff cannot overcome Delaware's learned intermediary doctrine. I will grant Defendant's summary judgment motion for this additional reason.

IV. CONCLUSION

Delaware law does not support Plaintiff's claim against Defendant, a brand name manufacturer that did not produce the product that Plaintiff ingested. Plaintiff is also unable to establish that an additional warning would have impacted his prescribing physician's decision to prescribe Risperdal. Thus, I will grant Defendant's Motion for Summary Judgment and enter judgment in Defendant's favor. As no claims remain pending in the case, I will also dismiss Defendant's *Daubert* motions as moot.

All Citations

Not Reported in Fed. Supp., 2019 WL 1571834

Footnotes

1 I use the brand name "Risperdal" to refer to the drug Plaintiff took. This is not meant to indicate whether Plaintiff took the brand name or a generic drug at any given time.

2005 WL 4052382
Only the Westlaw citation is currently available.
United States District Court,
W.D. Louisiana.

Patricia and Glenn TARVER
v.
WYETH, INC., et al

No. Civ.A.3-04-2036.
|
June 7, 2005.

Attorneys and Law Firms

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JUDGMENT

JAMES, J.

***1** For the reasons contained in the Report and Recommendation of the Magistrate Judge previously filed herein, and after an independent review of the entire record, and concurring with the Magistrate Judge's findings under the applicable law;

IT IS ORDERED that the defendant's motion for judgment on the pleadings, Doc. 36, is GRANTED and plaintiffs' claims against Schwarz are dismissed. THUS ORDERED AND SIGNED in Chambers at Monroe, Louisiana, on this *7* day of *June* 2005.

REPORT AND RECOMMENDATION

KIRK, Magistrate J.

Before the court is Defendant Schwarz Pharma Inc.'s (Schwarz) motion for judgment on the pleadings, Doc. # 36 referred to me by the district judge.

Facts

Schwarz developed and sold Metoclopramide, a pharmaceutical product used to treat, among other things, gastroesophageal reflux under the brand name Reglan. Plaintiff, Patricia Tarver, claims damages for ingestion of Metoclopramide but admits that she only ingested the generic version of the drug, not Reglan, manufactured by defendant Schwarz. Plaintiffs seek to impose liability on Schwarz even though it did not manufacture or sell the product used by plaintiff, Patricia Tarver. [1] Specifically, plaintiffs argue that, as the brand-name producer of the drug, Schwarz had a duty to warn all users of the drug, including users of its generic competitors' products, of the drug's dangers. Schwarz argues that such an action is precluded by the provisions of the Louisiana Products Liability Act (LPLA).

Plaintiff alleges she took generic Metoclopramide from 1998 to 2003 for gastroesophageal reflux disease pursuant to prescriptions from two medical doctors. As a result she alleges that she developed tardive dyskinesia, a movement disorder which affects the muscles and is caused by certain drugs. She claims that the package insert fails to warn doctors and patients of the significant risks associated with taking the drug for longer than twelve weeks, although it was, she asserts, well known to the companies who made or sold the drug that the drug may cause difficulties when so used.

Motion for Judgment on the Pleadings

Because an answer was filed, defendant, Schwarz, has properly raised the defense of failure to state a claim upon which relief can be granted by motion for judgment on the pleadings under Rule 12(c).

The motion for judgment on the pleadings is governed by the same standard as the 12(b)(6) motion to dismiss. *Johnson v. Johnson,* 385 F.3d 503 (5th Cir.2004).

In considering a motion to dismiss, the court must assume the truth of factual allegations of the complaint and liberally construe them in favor of the plaintiff. *Nicastro v. Clinton,* 882 F.Supp. 1128, *affirmed* 84 F.3d 1446. The complaint should not be dismissed unless it appears beyond doubt that plaintiff can prove no set of facts in support of his claim which would entitle him to relief. *Strother v. Southern California Permanente Medical Group.* 79 F.3d 859 (9th Cir. Cal.1996). In deciding the motion to dismiss, the function of the district court is to test the legal sufficiency of the complaint. *City of Toledo v. Beazer Materials and Services, Inc.,* 833 F.Supp. 646 (N.D.Ohio 1993).

***2** A motion to dismiss an action for failure to state a claim admits the facts alleged in the complaint, but challenges plaintiff's right to relief based upon those facts. *Crowe v. Henry,* 43 F.3d 198, 203 (5th Cir.1995). In particular, a complaint should not be dismissed for failure to state a claim unless it appears beyond a doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief. *Hirras v. National R.R. Passenger Corp.,* 10 F.3d 1142, 1144 (5th Cir.1994), *vacated on other grounds,* 512 U.S. 1231, 114 S.Ct. 2732, 129 L.Ed.2d 855 (1994); *Doe,* 753 F.2d at 1102. On a motion to dismiss, it is presumed that general allegations embrace the specific facts that are necessary to support the claim. *National Organization for Women, Inc. v. Scheidler,* 510 U.S. 249, 114 S.Ct. 798, 803, 127 L.Ed.2d 99 (1994), *citing Lujan v. Defenders of Wildlife,* 504 U.S. 555, 112 S.Ct. 2130, 2137, 119 L.Ed.2d 351 (1992).

Analysis

In Louisiana, the LPLA provides the exclusive theories of liability of manufacturers for damage caused by their products. La. R.S. 9:2800.52. A claimant may not recover on the basis of any theory not set forth in the LPLA. *Jefferson v. Lead Indus. Assoc., Inc.* 106 F.3d 1245, 1250-51 (5th Cir.1997). To maintain an action under any of the theories, a plaintiff must establish that the defendant is the manufacturer of the product. *Stahl v. Novartis Pharmaceuticals Corp.,* 283 F.3d 254, 260-261 (5th Cir.2002).

Here, plaintiff attempts to hold liable a company who is not the manufacturer of the product by asserting that it had a duty to warn of the product's dangers. Plaintiffs argue that generic manufacturers "have taken the position" in past litigation, that they are prohibited by the Food and Drug Administration (FDA) from changing the warnings created by the brand-name manufacturer. They argue that, if that is so, there would be no liability against the generic manufacturer for failure to warn and, if liability is not imposed on the brand-name manufacturer, an injured plaintiff would have no recourse.

First, if the generic manufacturers have taken that position, it is not clear to the court that they are correct, for 21 CFR 314.94(a)(8) expressly provides for changing the labeling, with certain limitations. However, the court need not and does not decide that issue now, without the benefit of thorough briefs by the parties on that issue. However, even if plaintiff is without a remedy, that is an issue for the FDA or, in this case, the Louisiana legislature, not the courts. The law is clear that Louisiana imposes on a manufacturer no duty to warn of the dangers of another company's product. *Fricke v. Owens-Corning Fiberglass Corp.,* 618 So.2d 473 (La.App.1993); *Roberts v. Bioplastics,* 93-2967, 2000 WL 34487072 (E.D.La., 2000). The fact that the defendant here is a pharmaceutical manufacturer subject to government regulations, as plaintiff argues distinguishes this case, is irrelevant.

***3** In a very well-written, thorough, and thought provoking brief, plaintiffs' counsel makes persuasive public policy arguments, and, citing the Restatement of Torts, argues that a negligent misrepresentation claim should be recognized in Louisiana based upon foreseeability and duty-risk analysis. Plaintiffs' counsel suggests that this is not a products claim subject to the limitations of the LPLA but is a negligent misrepresentation claim.

The claim in this case is that plaintiff was injured by a product which should not have injured her. It is, therefore, a products liability case, regardless of who are the defendants. It is, therefore, subject to the LPLA and its exclusive theories of liability. Plaintiffs' claims against Schwarz, who neither manufactured nor sold the drug plaintiff took, should be dismissed.

For the foregoing reasons, IT IS RECOMMENDED that Schwarz' motion for judgment on the pleadings be GRANTED and plaintiffs' claims against Schwarz dismissed.

OBJECTIONS

Under the provisions of 28 U.S.C. § 636(b)(1)(C) and Fed.R.Civ.P. 72(b), the parties have ten (10) business days from service of this Report and Recommendation to file specific, written objections with the clerk of court. A party may respond to another party's objections within ten (10) days after being served with a copy thereof. A courtesy copy of any objection or response or request for extension of time shall be furnished to the district judge at the time of filing. Timely objections will be considered by the district judge before he makes his final ruling.

FAILURE TO FILE WRITTEN OBJECTIONS TO THE PROPOSED FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS CONTAINED IN THIS REPORT WITHIN TEN (10) BUSINESS DAYS FROM THE DATE OF ITS SERVICE SHALL BAR AN AGGRIEVED PARTY, EXCEPT UPON GROUNDS OF PLAIN ERROR, FROM ATTACKING ON APPEAL THE UNOBJECTED-TO PROPOSED FACTUAL FINDINGS AND LEGAL CONCLUSIONS ACCEPTED BY THE DISTRICT JUDGE.

THUS DONE AND SIGNED in chambers, in Alexandria, Louisiana, on this the 27^{th} day of April 2005.

All Citations

Not Reported in F.Supp.2d, 2005 WL 4052382

Footnotes

1 Plaintiffs concede that all causes of action except the fifth cause of action (failure to warn) should be dismissed.

2020 WL 616575
Only the Westlaw citation is currently available.
United States District Court, D. Delaware.

Augustus Hebrew EVANS, Jr., Plaintiff,
v.
JOHNSON AND JOHNSON COMPANY, et al., Defendants.

Civil Action No. 14-1316-RGA
|
Signed 02/10/2020

Attorneys and Law Firms

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Todd C. Schiltz, Drinker Biddle & Reath LLP, Wilmington, Delaware; Daniel J. Brown and Hayley J. Reese, McCarter & English, LLP, Wilmington, Delaware; Counsel for Defendants.

MEMORANDUM OPINION

ANDREWS, U.S. District Judge

***1** Plaintiff Augustus Hebrew Evans, Jr., an inmate at the James T. Vaughn Correctional Center in Smyrna, Delaware, who appears *pro se*, filed this action in the Superior Court of the State of Delaware in and for Kent County, raising claims under Delaware law. The matter was removed to this Court on October 16, 2014. (D.I. 1). The First Amended Complaint is the operative pleading. (D.I. 44). Before the Court are the motion for summary judgment filed by Defendants Janssen Pharmaceuticals, Inc. and Johnson & Johnson (improperly named as Johnson and Johnson Company) and numerous other motions filed by the parties. (D.I. 215, 218, 220, 221, 224, 225, 233, 236).

I. PROCEDURAL AND FACTUAL BACKGROUND

Plaintiff is one of several inmates housed within the Delaware Department of Correction who have filed lawsuits against the manufacturers of Risperdal [1] alleging side effects occurred after taking the medication. Early on, Plaintiff was provided counsel. (*See* D.I. 13). In October 2017, Plaintiff filed a motion to proceed *pro se.* The motion was granted on November 6, 2017, and Plaintiff's counsel withdrew. [2] (D.I. 89).

The First Amended Complaint alleges seven counts: negligence, negligent misrepresentation, breach of warranty, breach of implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, breach of express warranty, and fraud by concealment, all arising out of Defendants' development, marketing, and sale of the drug Risperdal. (D.I. 44.) Plaintiff's First Amended Complaint alleges that he experienced "significant bodily and mental injury, disfigurement, embarrassment, and inconvenience" as a result of taking the drug. (D.I. 44 at ¶¶ 20, 25, 30, 35, 40, 44, 49).

Risperdal is approved for treatment of schizophrenia and bipolar disorder. (D.I. 227-1 at Ex. E. at 55). Janssen is the manufacturer of the brand name drug Risperdal. (*Id.* at Ex. E) Generic versions of Risperdal are referred to as risperidone. (*Id.* at Ex. C). Other drug manufacturers such as Teva Pharmaceuticals USA manufacture and sell risperidone. (*See* D.I. 227-1 at Ex. C [FDA approval of Teva's generic risperidone on June 30, 2008]). Warnings and precautions when taking Risperdal include: cerebrovascular events, neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia and diabetes

mellitus, hyperprolactinemia,[3] orthostatic hypotension, potential for cognitive and motor impairment, seizures, dysphagia, priapism, thrombotic thrombocytopenic purpura, disruption of body temperature regulation, antiemetic effect, suicide, increased sensitivity in patients with Parkinson's disease or those with dementia with Lewy bodies, and diseases or conditions that could affect metabolism or hemodynamic responses. (D.I. 227-1 at Ex. E at 55). The most common adverse reactions in clinical trials were somnolence, increased appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, increased saliva, constipation, fever, Parkinsonism, dystonia, abdominal pain, anxiety, nausea, dizziness, dry mouth, tremor, rash, akathisia, and dyspepsia. (*Id.*).

***2** Plaintiff testified that he was prescribed Risperdal from approximately April 2007 until April 2008 when he was housed at the Howard R. Young Correctional Institution, although he has no medical records relating to that time period. (D.I. 227-1 at Ex. G at 125-26 [Dep. Tr. at 48, 50]). Plaintiff testified that in deciding to take Risperdal he did not rely on anything from Janssen or Johnson & Johnson; he relied upon his doctor. (*Id.* at 146). His medical records indicate that he was prescribed Risperdal or risperidone from July 23, 2008 through January 14, 2009 and, again, for approximately two weeks in November 2011. (*Id.* at Ex. A at 4-10, 12, 13, 14, 15, 18-19; Ex. B at 26). The July 23, 2008 psychiatric progress note, authored by psychiatrist Anthony Cannuli, indicates that Risperdal was prescribed to treat agitation, that the risks and benefits of the medication were discussed with Plaintiff, that Plaintiff accepted the medication, and that he signed a consent. (*Id.* at Ex. A at 18-19). Medical records indicate that Plaintiff's physicians ordered Risperdal in July and October 2008, January 2009, and November 2011, and specifically note that Plaintiff was given risperidone (not Risperdal) in September, October, November, and December 2008, and November 2011.[4] (D.I. 227-1 at Ex. A at 4, 8, 9, 10, 12, 13, 14; Ex. B at 26). Plaintiff's medical records refer to the administration of Risperdal for a one-month period from August 1 to August 31, 2008. (*Id.* at Ex. A at 15). Plaintiff submitted a medical grievance in June 2014, claiming that "he has increase in his nipples and lumps because of the drug Risperdal." (D.I. 230 at 20). The RN's chart review states, "no order in chart for Risperdal since 7/25/13." (*Id.*).

Plaintiff testified that his injuries included "temporary gynecomastia,"[5] weight gain, enlarged and/or elongated nipples, elevated prolactin levels, pituitary tumor,[6] tardive dyskinesia (including allegedly associated tremors and twitches),[7] increased risk of death from heart attack,[8] "diabetes hyperglycemia, and other blood sugar side effects,"[9] suicidal thoughts,[10] abdominal pain and decreased activity associated with respiratory infections,[11] dry skin,[12] joint pain,[13] sore throat,[14] headaches,[15] blurred vision,[16] and memory lapse.[17] (D.I. 227-1, Ex. G at 133-144).

II. LEGAL STANDARD

***3** "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586-87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations ..., admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence ... of a genuine dispute ...." Fed. R. Civ. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247-49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

Defendants move for summary judgment on the grounds that: (1) Plaintiff lacks evidence that he consumed Janssen's product, which is the branded drug, Risperdal, as opposed to generic risperidone; (2) the claims are time-barred; (3) Plaintiff does not have the expert testimony that is required to prove causation and to establish a product defect; (4) Plaintiff cannot satisfy the learned intermediary doctrine; (5) Plaintiff does not have evidence of a communication upon which he or his physician relied; (6) Plaintiff has not identified a special purpose in connection with the implied warranty of fitness for a particular purpose claims; (7) Plaintiff's fraud by concealment claim fails because Plaintiff cannot identify an affirmative act of concealment; and (8) Plaintiff's label adequacy arguments are preempted. (D.I. 226).

Plaintiff responds that each of the seven claims is founded upon Defendants' promotion and marketing of Risperdal for off-label purposes for which the drug had neither been tested nor approved and Defendants' failure to warn that the drug should be used as prescribed and not be prescribed for off-label purposes. (D.I. 230 at 6).

III. DISCUSSION

A. Learned Intermediary Doctrine

To succeed on his two negligence-based claims against Defendants, Plaintiff must overcome the learned intermediary doctrine. Defendants argue that Plaintiff cannot satisfy the doctrine.

***4** The learned intermediary doctrine is an exception to the general rule that a manufacturer owes a duty to directly warn a consumer of the risks associated with a product. *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399 (Del. 1989). Specifically, "a manufacturer of a prescription drug satisfies its duty to provide an appropriate warning about the drug when it gives the patient's physician the necessary information to be disseminated to the patient." *Id.* (emphasis omitted). The doctrine is inapplicable if a warning is "inadequate as a matter of law." *Barba v. Carlson,* 2014 WL 1678246, at *2 (Del. Super. Ct. Apr. 8, 2014). Warnings are not inadequate as a matter of law if there is "a genuine issue of material fact about whether the warnings were adequate." *Id.* at *2-3. To maintain an action against a manufacturer when such a genuine factual dispute exists, a plaintiff must show that an additional warning would have made a difference to the plaintiff's treating physician. *Id.* at *3; *Barba v. Bos. Sci. Corp.,* 2015 WL 6336151, at *6 n.22 (Del. Super. Ct. Oct. 9, 2015) (clarifying that the inquiry employs a subjective test). This is because, if a more complete warning would not have made a difference to the prescriber, a plaintiff is unable to prove but for causation. *See Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014); *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008); *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098-99 (5th Cir. 1991); *In re Plavix Mktg., Sales Practices & Prod. Liab. Litig*, 2017 WL 4838842, at *6 (D.N.J. Oct. 26, 2017).

Plaintiff's factual allegations are insufficient to escape the application of the learned intermediary doctrine. Plaintiff argues, without citation to any legal authority, that the Risperdal label was inadequate as it did not warn against off-label prescription and does not warn against "cancerous cellulitis and/or lipoma." (D.I. 230 at 3-4, 15-16). Plaintiff's argument, with nothing more, fails to provide any evidence to establish that Defendants' warnings were inadequate as a matter of law.

Since Plaintiff cannot show inadequacy as a matter of law, he must show that an additional warning would have made a difference to his prescribing physicians. Plaintiff cannot make such a showing. Plaintiff's prescribing physician, Dr. Cannuli, was not deposed. Plaintiff seems to argue that he did not depose Dr. Cannuli because he was confused about discovery deadlines and/or there was a conflict with his prior attorney about deposing the physician. (D.I. 230 at 16).

The record, however, reflects Plaintiff's knowledge of deadlines imposed by the Court. After Plaintiff opted to proceed *pro se*, he was advised in the November 6, 2017 Order that the case would proceed on the deadlines set forth in the July 28, 2017 Order, which included a December 15, 2017 discovery deadline. (D.I. 82; D.I. 89). Following the November 15, 2017 Order, Plaintiff sought discovery from Defendants (D.I. 92). He then proceeded to file a number of motions seeking extensions of time and discovery, many of them complaining about defense counsel's tactics. (*See* D.I. 169 at 2-6).

The record also reflects that when Plaintiff sought to remove his attorney and proceed pro se, he made no mention of deposition disputes with his attorney. Rather, he complained that his attorney withheld information and failed to forward discovery to him. (D.I. 86). When Plaintiff, after the discovery cut-off, on January 17, 2018, sought funds to conduct depositions of "important defendants" (D.I. 132), he made no mention that he sought to depose his own physicians (who are not "defendants.").

Plaintiff has no evidence that, but for the supposedly inadequate warning, he would not have been prescribed Risperdal. Hence, Defendants are shielded from liability by the learned intermediary doctrine. I will grant Defendants summary judgment on this basis on the negligence-based Counts One and Two.

B. Proximate Cause

Plaintiff alleges in Counts One and Two that he was injured as a direct and proximate result of his ingestion of Risperdal when Defendants were negligent in the marketing, distribution, sale, and misrepresentation of Risperdal in failing to warn physicians and users of adverse risks associated with its use and in making false and/or misleading statements regarding the safety of Risperdal. To prevail on his negligence claims, Plaintiff must prove that Risperdal proximately caused him harm. *Culver v. Bennett*, 588 A.2d 1094, 1097-98 (Del. 1991) (discussing Delaware's "but for" rule of proximate cause in negligence cases). A determination of the proximate cause of a specific instance of a disease or medical condition must "rest upon the individualized findings and opinion of a trained physician." *Money v. Manville Corp. Asbestos Disease Comp. Jr. Fund*, 596 A.2d 1372, 1376 (Del. 1991). "General causation" addresses the question of whether a particular substance is capable of causing a particular harm. *Hopkins v. Janssen Pharm., Inc.*, 2019 WL 1567840, at *2 n.3 (D. Del. Apr. 11, 2019). "Specific causation" addresses the related question of whether a particular substance caused a particular harm to a particular person. *Id.* "A plaintiff's bald assertion that he has a condition and that the condition was caused by a certain drug are insufficient." *Id.* at *2.

***5** Defendants argue that Plaintiff must establish his use of Risperdal was the proximate cause of his alleged injuries. [18] Defendants further argue that because Plaintiff lacks an expert report addressing specific causation (*i.e.*, that his use of Risperdal caused his alleged injuries), summary judgment is appropriate on their behalf. (D.I. 226 at 17-18). I agree.

Plaintiff concedes that he does not have expert testimony and as a matter of law cannot establish causation. (D.I. 230 at 16). Plaintiff argues, however, that the Court did not help him in obtaining an expert witness, which prejudiced his case. (*Id.*). On May 8, 2018, the Court addressed the issue of an expert and denied Plaintiff's motion following a review of Plaintiff's filings and finding that he failed to make a sufficient showing to warrant appointment of an expert witness. (D.I. 169 at 6; D.I. 170). Plaintiff did not seek reconsideration of that order. Plaintiff's second motion was denied for the same reasons. (*See* D.I. 212; D.I. 213). At the same time as the second denial, the Court set a new dispositive motion deadline of July 10, 2019. (*See* D.I. 213). Plaintiff filed an interlocutory appeal, but he did not raise the issue of appointment of an expert witness on appeal. [19] (*See* D.I. 214). Nor did Plaintiff seek reconsideration of the denial of his second request for appointment of an expert witness. On June 24, 2019, less than a month before the dispositive motion deadline, Plaintiff filed a renewed motion for appointment of an expert and/or for funds for an expert. (D.I. 218). It is currently pending and, based upon the reasoning denying the first and second motions, will also be denied.

***6** Plaintiff was provided competent counsel who ably represented him, yet Plaintiff opted to proceed *pro se.* Plaintiff has the right to proceed *pro se*, but his decision has negative consequences as evidenced by the lack of an expert witness needed to establish "specific causation." (*See, e.g.*, D.I. 169 at 4) Evidence of only "general causation" is insufficient to establish a negligence claim under Delaware law and, based upon the evidence of record, even that is lacking. Plaintiff's own testimony is

that his physicians did not directly connect the use of Risperdal to Plaintiff's medical conditions. Thus, I will grant Defendants' motion for summary judgment on Counts One and Two for lack of proximate cause.

C. Brand Name Liability for Plaintiff's Use of Generic Risperidone

Defendants seek summary judgment on the negligence claims (*i.e.*, Counts One and Two) on the grounds that Plaintiff cannot establish that his alleged injuries resulted from the use of the brand name drug Risperdal. (D.I. 226 at 14-15). Defendants argue that Plaintiff testified a pharmacy record obtained by his prior counsel documented the use of the brand name Risperdal, but the evidence of record does not support Plaintiff's testimony. (*Id.* at 15). Plaintiff argues that Defendants' agents denied him discovery from 2001 through 2014, the record suggests he was administered the generic brand in 2011 and, in dispute, is whether he was administered the generic brand between 2008 through 2011. (D.I. 230 at 13). Plaintiff also argues that a Delaware law for the substitution of medication did not go into effect until 2014. (*Id.*). Plaintiff relies upon 24 Del. C. § 2549A to support his position. The statute, however, is inapplicable to Plaintiff's claim as it applies to the prescription of biological products.

Under federal law, brand name and generic drug manufacturers are not equally responsible for drug labeling. "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (citations omitted). This regulatory reality led the Supreme Court in *PLIVA* to find that federal law preempts state tort liability for a generic drug manufacturer's inadequate label. *Id.* at 623-24.

Delaware is among the states that have passed laws permitting pharmacists to substitute generic drugs without a patient's consent to save costs. *See* 24 Del. C. § 2549. A name brand need be dispensed only if the physician specially directs the patient receive a brand name. *Id.* at ¶ 2549(a)(1) & (c). The law went into effect July 24, 2007, prior to the time Plaintiff was first prescribed Risperdal.

In *Trower v. Janssen Pharms., Inc.*, 2019 WL 1571834, *2-4 (D. Del. Apr. 11, 2019), I examined Delaware's products liability law. As I explained more fully there, Delaware law does not support a claim against a brand name drug manufacturer for a plaintiff's use of a generic drug. *See In re Benzene Litig.*, 2007 WL 625054, at *6 (Del. Super. Ct. Feb. 26, 2007) (to state a claim in a products liability case, a plaintiff must plead facts that identify the defective product and the manufacturer of that product); *Lee v. A. C. & S., Inc.*, 1986 WL 15421, at *2 (Del. Super. Ct. Dec. 15, 1986) ("generic identification of a product is not enough to establish liability absent some other evidence that that generic product was the specific product of a defendant")(asbestos context). *See also Strayhorn v. Wyeth Pharms.*, 737 F.3d 378, 406) (6th Cir. 2014) ("[E]very federal court of appeals to consider this issue has held that brand-name manufacturers are not liable to plaintiffs who are injured by a generic manufacturer's drug, whether under a state's product-liability act or under general principles of duty.").

***7** The evidence of record is that prescriptions were written for Risperdal. However, the only evidence that Plaintiff was administered Risperdal is the August 2008 medication administration record. The medication administration records for September, October, November, and December 2008, and November 2011 indicate that Plaintiff was administered risperidone. There is no evidence of record of the medication administered to Plaintiff during 2009, 2010, and January through October 2011.

At most, the record reflects that Plaintiff was given Risperdal during the month of August 2018. Plaintiff's position, without evidentiary support, that he was given Risperdal from 2008 through 2011 does not suffice to defeat Defendants' motion for summary judgment on this issue. Accordingly, I will grant Defendant's motion for summary judgment on Counts One and Two, with the exception of the administration of Risperdal during the month of August 2008.

D. Negligent Misrepresentation, Breach of Express Warranty

Count Two raises a claim for negligent misrepresentation and Count Six raises an express warranty claim. Defendants move for summary judgment on the grounds that there is no evidence that Dr. Cannulli relied on Defendants' judgment or superior skill in deciding to prescribe Risperdal for Plaintiff and there is no evidence that Defendants made an express warranty to Dr. Cannulli.

Counts Two and Six both require evidence of communication and reliance.

To prevail on a negligent misrepresentation claim, Plaintiff must show:

> the defendant had a pecuniary duty to provide accurate information, (2) the defendant supplied false information, (3) the defendant failed to exercise reasonable care in obtaining or communicating the information, and (4) Plaintiff suffered a pecuniary loss caused by justifiable reliance upon the false information.

Dunn v. FastMed Urgent Care, P.C., 2019 WL 4131010, at *12 (Del. Ch. Aug. 30, 2019). A plaintiff cannot sustain a claim of negligent misrepresentation when he has failed to produce any evidence that the defendant supplied false information. *See Coleman v. Pricewaterhousecoopers LLC*, 2005 WL 1952844, at *3 (Del. Super. Ct. July 29, 2005).

Under Delaware law, claims for breach of an express warranty are governed by the Uniform Commercial Code. *See Bell Sports, Inc. v. Yarusso*, 759 A.2d 582, 592 (Del. 2000) (express warranty provisions of Delaware law are "identical" to UCC provisions). [20] "In order to pursue a claim for breach of express warranty, the consumer must produce evidence of reliance on the express warranty." *Barba v. Carlson*, 2014 WL 1678246, at *5 (Del. Super. Ct. Apr. 8, 2014).

***8** Plaintiff opposes summary judgment on both counts. He argues that there was a confusing discovery schedule, which I addressed at pages 9-10. He also argues, without supporting evidence, that his physician was influenced by Defendants' off-label promotions and that Dr. Cannulli prescribed Risperdal for an off-label condition. "Because the [Food, Drug, and Cosmetic Act] does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (recognizing off-label usage as "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.")). There is no evidence that Plaintiff relied upon any representations by Defendants, that Defendants made an express warranty to Plaintiff, or that Defendants made an express warranty to Plaintiff's physicians concerning the use of Risperdal to treat off-label conditions. [21] There simply is no evidence to support Plaintiff's claims. Therefore, I will grant Defendants' motion for summary judgment on the claims of Counts Two and Six.

E. Implied Warranty Claims

Count Three raises a breach of warranty claim (construed as a breach of implied warranty), Count Four raises a breach of implied warranty of merchantability claim, and Count Five raises a breach of implied warranty of fitness for a particular purpose claim. Defendants seek judgment on the grounds that Counts Three, Four, and Five are time-barred. [22]

***9** In Delaware, all actions for breach of an implied warranty are limited by the provisions set forth in § 2–725 of Title 6 of the Delaware Code. *Addison v. Emerson Elec. Co.*, 1997 WL 129327, at *3 (D. Del. Feb. 24, 1997) (citing *Johnson v. Hockessin Tractor, Inc.*, 420 A.2d 154, 158 (Del. 1980)). This section provides for a four-year statute of limitations and applies even in cases involving personal injuries. *Id.* The cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge. *LTL Acres LP. v. Butler Manuf. Co.*, 2016 WL 7336862, at *2 (Del. Super. Ct. Dec. 16, 2016). The breach occurs when the goods are delivered. *Id.*

Plaintiff argues, without evidentiary support, that he last used Risperdal in July 2013. Plaintiff relies upon a June 2014 medical grievance, which states that a chart review indicated that Risperdal had not been ordered for Plaintiff since July 25, 2013. This

grievance report, however, does not indicate that Plaintiff was administered Risperdal. The evidence of record indicates that Plaintiff was administered Risperdal in August 2008, and not on other dates. Plaintiff did not commence this action until 2014. His implied warranty claims are therefore clearly time-barred. I will grant Defendants' motion for summary judgment on these claims. [23]

F. Fraud by Concealment

Count Seven alleges that Defendants knowingly and intentionally concealed, suppressed and/or omitted important information to physicians and consumers regarding the safety of Risperdal. Defendants move for summary judgment on the grounds that there is no evidence of any affirmative action by Defendants to conceal any of alleged side effects Plaintiff claims to have experienced or to conceal any alleged fraud.

To establish a claim for fraudulent concealment or intentional misrepresentation, Plaintiff must show:

> (1) Deliberate concealment by the defendant of a material past or present fact, or silence in the face of a duty to speak; (2) That the defendant acted with scienter; (3) An intent to induce plaintiff's reliance upon the concealment; (4) Causation; and (5) Damages resulting from the concealment.

Nicolet, Inc. v. Nutt, 525 A.2d 146, 149 (Del. 1987).

Plaintiff argues that Defendants' off-label promotions concealed facts that the drug was not tested or approved for uses not listed. He also argues that the warning labels were not adequate. The evidence of record does not support Plaintiff's claim. Notably, Plaintiff testified that he had no communication with Defendants before filing this action and, in deciding to take Risperdal, he did not rely on anything from Janssen or Johnson & Johnson. (D.I. 227-1 at Ex. G at 145, 146). Rather, he relied upon his physician. I will therefore grant Defendants' motion for summary judgment on this issue.

IV. MISCELLANEOUS MOTIONS

***10** There are a number of motions filed by the parties. I will deny Plaintiff's letter/motion for issuance of subpoenas and for a hearing. (D.I. 215). The discovery deadline has passed. For the same reason, I will dismiss as moot Defendants' motion for a protective order for subpoenas. (D.I. 224).

Plaintiff again has filed a motion to appoint an expert. (*See* D.I. 218). I will deny the motion for the reasons set forth in the Court's earlier orders. (*See* D.I. 169; D.I. 170; D.I. 212; D.I. 213). In addition, I note from Plaintiff's deposition testimony that his treating physicians did not directly associate his alleged medical issues with the use of Risperdal.

I will deny Plaintiff's motion for leave to amend and to extend discovery. (D.I. 220). Plaintiff did not comply with the Local Rules of this court in seeking leave to amend. Plaintiff is well aware of this Rule given that the Court referred to it in a 2017 order striking Plaintiff's Amended Complaint that he filed without leave. (*See* D.I. 95). Plaintiff seems to seek to amend based upon "knowledge gleaned" from discovery provided him, but does not indicate which portions of the Amended Complaint he wishes to amend or why it is necessary. In addition, Plaintiff has been given ample time to conduct discovery. Therefore, I will deny his request to extend the discovery deadline.

Plaintiff has filed numerous requests for counsel. (D.I. 218; D.I. 221; D.I. 233; D.I. 236). I will deny his requests. Early in this litigation, the Court referred this matter to the Federal Civil Panel and, on July 28, 2015, the Court recognized the agreement of representation by an attorney for Plaintiff. (*See* D.I. 13; D.I. 17). On October 12, 2017, Plaintiff filed a motion to proceed *pro se.* (D.I. 85). The Court was advised by Plaintiff's counsel that the attorney-client relationship had deteriorated. (D.I. 87).

Plaintiff's reasons for returning to *pro se* status were that his attorney withheld information and failed to forward him discovery. This same attorney ably represented several other inmates who filed complaints over their use of Risperdal. After Plaintiff opted to return to *pro se* status, the Court made various rulings to make it possible for Plaintiff to obtain and review the discovery that seemed most important to him. (*See* D.I. 169; D.I. 170, D.I. 194; D.I. 212; D.I. 213).

If the district court determines that a plaintiff's claim has arguable merit in fact and law, the court considers a number of additional factors that bear on the need for appointed counsel including: (1) the plaintiff's ability to present his own case, (2) the complexity of the legal issues, (3) the degree to which factual investigation will be necessary and the ability of the plaintiff to pursue investigation, (4) the plaintiff's capacity to retain counsel on his own, (5) the extent to which a case is likely to turn on credibility determinations, and (6) whether the case will require expert witness testimony. *See Tabron v. Grace*, 6 F.3d 147 (3d Cir. 1993).

As observed by Delaware courts, Plaintiff is "a prolific litigant who has gained notoriety among the Delaware courts." *Evans v. Genentech, Inc.*, 2015 WL 310248, at *1 (Del. Super. Ct. Jan. 23, 2015). He has filed eleven additional federal lawsuits in this Court since the instant case was removed to this Court. Plaintiff testified that prior to his incarceration he graduated from a paralegal course. (*See* D.I. 223-1 at 70-71). Although certain issues raised by Plaintiff would have required supportive expert testimony in order for Plaintiff to have been able to proceed, Plaintiff's own deposition testimony is that none of his physicians determined his medical conditions were necessarily related to the use of Risperdal, which supports my conclusion that Plaintiff's claims do not have arguable merit in fact. In addition, Plaintiff was afforded counsel, but opted to proceed *pro se.* He is a frequent litigator and has the ability to present, and has ably presented, his own case. Furthermore, viable claims of the type he raises are the sort that lawyers routinely take on a contingency basis. Plaintiff probably knows this. (*See* D.I. 218 at 9 ("Free Risperdal Lawsuit Evaluation: If you or a loved one has been injured by Risperdal, you should contact our law firm immediately. You may be entitled to compensation by filing a lawsuit and we can help." (emphasis in original))). Plaintiff could have sought counsel of his own choice; there is nothing in the record that he ever tried. In light of the foregoing, I will deny Plaintiff's requests for counsel.

V. CONCLUSION

***11** Based upon the above discussion, the Court will: (1) deny Plaintiff's letter/motion for issuance of subpoenas and for a hearing (D.I. 215), motion for appointment and/or funds for expert (D.I. 218), motion for leave to amend (D.I. 220), and requests for counsel (D.I. 218; D.I. 221; D.I. 233; D.I. 236); (2) dismiss as moot Defendants' motion for protective order (D.I. 224); and (3) grant Defendants' motion for summary judgment (D.I. 225).

A separate order shall issue.

All Citations

Slip Copy, 2020 WL 616575

Footnotes

1 I use the brand name "Risperdal" to refer to the drug Plaintiff took. This is not meant to indicate whether Plaintiff took the brand name or a generic drug at any given time.

2 Currently pending are four requests for counsel filed by Plaintiff. (*See* D.I. 218; D.I. 221; D.I. 233; D.I. 236).

3 Risperdal is associated with higher levels of prolactin elevation than other antipsychotic agents. (D.I. 227-1 at Ex. E at ¶ 5.6). Gynecomastia has been reported in patients receiving prolactin-elevating compounds. (*Id.*). Gynecomastia is the enlargement of the male breast gland due to a hormonal imbalance. *See Trower v. Janssen Pharm., Inc.*, 2019 WL

1571834, at *1 (D. Del. Apr. 11, 2019). Prolactin is a hormone which enhances breast development and initiates lactation in the human (typically female) body. (*See id.*).

4 The parties did not provide Plaintiff's 2009 Medication Administration Records.

5 He does not assert that he has ever been diagnosed with gynecomastia. The First Amended Complaint does not make such an allegation. Nor does any declaration of Plaintiff, although in some of his filings he advances a theory that had a temporary form of gynecomastia that caused "super nipples." (*See* D.I. 90 at 4 [stricken amended complaint]; D.I. 157 at 10 [answering brief in opposing to motion for summary judgment]). Plaintiff submitted a copy of one of his medical grievances in connection with one of his requests for appointment of an expert. The medical grievance was denied on December 3, 2015, with the comment, "I reviewed the past grievances and the available medical record in iCHRT. [Plaintiff] has been complaining of gynecomastia following being prescribed Risperdal. He has been examined numerous times and no gynecomastia has been found. The examiners have described elongated nipples and [Plaintiff] has been recurrently requesting A&D ointment for his dry nipples. He also complains of being told he has a pituitary tumor. In Oct. 2014 Dr. Desrosiers told him he had an elevated prolactin level which was normal on repeat testing." (D.I. 218 at 18).

6 Plaintiff testified that he noticed the gynecomastia and weight gain no later than 2009. (D.I. 227-1 at Ex. G at 131). Plaintiff testified that his physician told him that his weight gain and "ballooning chest" had nothing to do with the medication he was taking. (*Id.*). Plaintiff testified that Dr. Desrosiers diagnosed that "his pituitary gland and other glands were operating fast." (*Id.* at 134).

7 Plaintiff testified that he first noticed sporadic and uncontrollable face twitching in 2013. (D.I. 227-1 at Ex. G at 135). He did not raise the problem with his healthcare providers. (*Id.*). Plaintiff testified that Dr. Desrosiers stated there was a possibility that Plaintiff's shoulder, eye, face and/or neck tremors were caused by Risperdal, but that other drugs could have also caused the tremors. (*Id.* at 139).

8 Plaintiff testified that none of his doctors told him that he had an increased risk of sudden death from heart attack due to Risperdal use. (D.I. 227-1 at Ex. G at 135). Plaintiff testified that he had chest pains before he began taking Risperdal. (*Id.*).

9 Plaintiff testified that his physicians could not find any medical reason behind his blood sugar issues, and they never associated the problem with Risperdal. (D.I. 227-1 at Ex. Gat 136).

10 When asked if he was bring a claim for suicidal thoughts, Plaintiff replied "yes and no, if that's possible." (D.I. 227-1 at Ex. G at 136). Plaintiff does not know if his feeling of hopelessness is because of Risperdal or something else because he has not seen a specialist who is "willing to seriously diagnose" him. (*Id.* at 137). Plaintiff testified that no doctor told him that Risperdal caused him to be suicidal. (*Id.*).

11 Plaintiff testified that he had a respiratory infection when he first started taking Risperdal and thought that Risperdal may, or may not, have been the cause of abdominal pain, decreased activity, and respiratory infections. (D.I. 227-1 at Ex. G at 137). Plaintiff testified that Dr. Desrosiers stated that his respiratory infections (he had three) could have come from taking Risperdal. (*Id.* at 140).

12 Plaintiff testified that he started having dry skin in 2009 and did not have skin issues before taking Risperdal. (D.I. 227-1 at Ex. G at 138). He testified that no physician directly told him that Risperdal caused dry skin, but Dr. Desrosiers stated it is one of the residual effects of the drug. (*Id.* at 139).

13 Plaintiff testified that he first experienced joint pain in 2013 and was told Risperdal causes joint pain. (D.I. 227-1 at Ex. G at 140). Dr. Desrosiers did not specifically say that Plaintiff's joint pain was caused by Risperdal although she classified it as one of the side effects of the drug. (*Id.*).

14 Plaintiff testified that he has not been told by a physician that Risperdal caused a sore throat. (D.I. 227-1 at Ex. G at 140, 141).

15 Plaintiff testified that he experienced headaches soon after taking Risperdal and that Dr. Desrosiers stated that it could be associated with Risperdal but other drugs Plaintiff was taking could have also caused headaches. (D.I. 227-1 at Ex. G at 141). At least five years had passed from the time the headaches started to the time Plaintiff saw Dr. Desrosiers. (*Id.*). A physician Plaintiff saw prior to seeing Dr. Desrosiers did not associate the headaches with Risperdal and thought the headaches could be related to stress or another drug Plaintiff was taking. (*Id.* at 142). Plaintiff testified that he has headaches when he is dehydrated. (*Id.*).

16 Plaintiff testified that he first experienced blurred vision when he started taking Risperdal, but that it became an issue when he started taking two other drugs – Celexa and Zyprexa. (D.I. 227-1 at Ex. G at 142). Dr. Desrosiers said that blurred vision could be associated with the use of Risperdal and was not necessarily the cause of Plaintiff's blurred vision. (*Id.*).

17 Plaintiff testified that he noticed memory issues in 2013. (D.I. 227-1 at Ex. G at 143). He was not taking Risperdal at the time. (*Id.*). Dr. Desrosiers told Plaintiff that memory lapse is a possible side effect from taking Risperdal, but no physician has told Plaintiff that his memory lapses are caused by Risperdal. (*Id.* at 144).

18 As discussed in footnotes 5 to 17, the evidence of record indicates that: Plaintiff does not have a diagnosis of gynecomastia; his once elevated prolactin levels are now normal; he was told by his physician that his weight gain and "ballooning chest" had nothing to do with the medication he was taking; he was told by his physician there was a possibility that his shoulder, eye, face and/or neck tremors were caused by Risperdal, but that other drugs could have also caused the tremors; none of his doctors told him that he has an increased risk of sudden death from heart attack as a result of using Risperdal; his physicians could not find any medical reason behind his blood sugar issues and they never associated the problem with Risperdal; no doctor told him that Risperdal caused him to be suicidal; he was told by Dr. Desrosiers that his respiratory infections could have come from taking Risperdal; no physician told him directly that Risperdal caused dry skin, but Dr. Desrosiers stated it is one of the residual effects of the drug; Dr. Desrosiers did not specifically say that Plaintiff's joint pain was caused by Risperdal but she classified it as one of the side effects of the drug; he has not been told by a physician that Risperdal caused sore throats; Dr. Desrosiers told him that headaches could be associated with Risperdal but other drugs Plaintiff was taking could have also caused headaches; a physician Plaintiff saw prior to Dr. Desrosiers did not associate the headaches with Risperdal and thought the headaches could be related to stress or another drug Plaintiff was taking; Dr. Desrosiers told him that blurred vision could be associated with the use of Risperdal but it was not necessarily the cause of Plaintiff's blurred vision; and Dr. Desrosiers told Plaintiff that memory lapse is a possible side effect from taking Risperdal, but no physician has told Plaintiff that his memory lapses are caused by Risperdal.

19 The appeal was dismissed upon Plaintiff's motion on July 25, 2019. (*See* D.I. 231).

20 Title 6, section 2–313(1) provides that express warranties of a seller of goods are created as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

(c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model. In addition, 6 Del. C. § 2–313(2) states that: It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

21 The Court takes judicial notice that Janssen, a subsidiary of Johnson & Johnson, entered into a plea agreement with the United States Department of Justice, and pled guilty to promoting Risperdal to health care providers for treatment of psychotic symptoms and associated disturbances exhibited by elderly, non-schizophrenic dementia patients, between March 3, 2002 and December 31, 2003. *See* https://www.justice.gov/usao-edpa/pr/janssen-pharmaceuticals-pleads-guilty-and-sentenced-misbranding (last visited Jan. 29, 2020). The issues to which Janssen pled guilty are not only different from the issues raised by Plaintiff in his Amended Complaint, but also took place during the different time-frame of 2002-03. The Court also takes judicial notice of Janssen's 2012 multi-state (including Delaware) consumer protection settlement, which alleged that Janssen promoted Risperdal, among a class of drugs known as atypical or second-generation antipsychotics, for off-label uses to both geriatric and pediatric populations, targeting patients with Alzheimer's disease, dementia, depression, and anxiety. *See* https://news.delaware.gov/2012/08/30/biden-announces-landmark-settlement-with-janssen-pharmaceuticals (last visited Jan. 29, 2020). The settlement was not an admission of wrongdoing or violation of any law or regulation. *See* https://www.jnj.com/media-center/press-releases/janssen-pharmaceuticals-inc-announces-risperdal-consumer-protection-settlement-with-36-states-and-the-district-of-columbia (last visited Jan. 29, 2020). The issues in

the multi-state consumer protection settlement are different from those issues raised by Plaintiff in his Amended Complaint.

22 Defendants also argue that Plaintiff's personal injury claims are time-barred. The Court does not decide summary judgment on this basis given that granting summary judgment is appropriate on other grounds. The Court notes, however, that in 2014, Plaintiff filed a lawsuit similar to this one in the Superior Court alleging that he "suffered adverse side-effects after taking a medication prescribed to him in prison." *Evans v. Genentech, Inc.*, 2015 WL 310248 (Del. Super. Ct. Jan. 23, 2015). He was prescribed medication in 2007 but it was not until 2014 that he became aware his symptoms could have been caused by the medication taken in 2007. The Superior Court dismissed the case as time-barred, noting that as early as 2006 the medical community was on notice of potential side effects resulting from the use of the medication, as was apparent from the drug's packaging insert.

23 Summary judgment is also appropriate on Count Four as Plaintiff lacks the required expert testimony. *See Reybold Grp., Inc. v. Chemprobe Tech., Inc.*, 721 A.2d 1267, 1269-70 (Del. 1998) (In a breach of warranty of merchantability claim, "[i]f the matter in issue is one within the knowledge of experts only and not within the common knowledge of laymen, it is necessary for the plaintiff to introduce expert testimony in order to establish a *prima facie* case" of the "defective" nature of the goods.). The Court addressed Plaintiff's lack of expert testimony at pages 11-12 when discussing proximate cause.

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United States District Court, D. Delaware.

Donte L. HOPKINS, Plaintiff,
v.
JANSSEN PHARMACEUTICALS, INC., Defendant.

Civil Action No. 1:14-cv-01366-RGA
|
Signed 04/11/2019

Attorneys and Law Firms

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MEMORANDUM OPINION

ANDREWS, U.S. DISTRICT JUDGE:

***1** Presently before me are Defendant's Motion for Summary Judgment (D.I. 143) and Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan. (D.I. 146). The Parties have fully briefed the issues. (D.I. 144, 147, 160, 161, 168, 170). I heard oral argument on March 7, 2019. For the reasons set out below, I will grant Defendant's Motion for Summary Judgment and dismiss as moot Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan.

I. BACKGROUND

Plaintiff suffered a traumatic brain injury at age five and has since suffered from serious mental illness. (D.I. 160 at 5). He has been diagnosed with suicidal ideation, schizophrenia, and bipolar disorder. (*Id.* at 6). Doctors have prescribed him Risperdal, [1] Haldol, Geodon, Prozac, and Zyprexa to treat those conditions. (*Id.*). Plaintiff was first prescribed Risperdal in June 2008 and remained on the drug until June 2010. (*Id.*). Plaintiff also took the drug for two months in early 2011 and from July 2012 to September 2014. (*Id.*).

Risperdal is FDA-approved for treatment of schizophrenia and bipolar disorder. (D.I. 144 at 5). Defendant is the manufacturer of brand name Risperdal. (D.I. 160 at 2). Risperidone is the generic name for Risperdal. (D.I. 144 at 2). Other drug manufacturers, such as Zydus Pharmaceuticals (USA), Inc. or Torren Pharmaceuticals Ltd., manufacture and sell risperidone. (*Id.* at 5).

Gynecomastia is a potential side effect of Risperdal. (D.I. 160 at 3-4). Increased levels of prolactin may also be a side effect and is allegedly connected to an increased risk of gynecomastia. (D.I. 147 at 8). Gynecomastia is the enlargement of the male breast gland due to a hormonal imbalance. Prolactin is a hormone which enhances breast development and initiates lactation in the human (typically female) body.

Plaintiff filed this lawsuit on November 3, 2014. (D.I. 3). He asserted seven claims against Defendant based on its marketing and sale of Risperdal: negligence (Count I), negligent misrepresentation (Count II), breach of warranty (Count III), breach of

the implied warranty of merchantability (Count IV), breach of the implied warranty of fitness for a particular purpose (Count V), breach of express warranty (Count VI), and fraud by concealment (Count VII). (D.I. 39 at 3-7). He alleges that because of Defendant's conduct, he developed gynecomastia and pus bumps. (D.I. 144 at 6).

Defendant filed the present motions on October 12, 2018. It sought summary judgment on each count of the first amended complaint. (D.I. 39). In response to Defendant's summary judgment motion, Plaintiff voluntarily withdrew Counts III-VII. (D.I. 160 at 1 n.1). Thus, the only Counts remaining are negligence and negligent misrepresentation.

II. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey,* 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

***2** The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations ..., admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence ... of a genuine dispute ...." Fed. R. Civ. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris,* 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247-49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

III. DISCUSSION

A. Proximate Cause

To prove his remaining negligence claims, Plaintiff must prove that Risperdal proximately caused him harm. *Culver v. Bennett,* 588 A.2d 1094, 1097-98 (Del. 1991) (discussing Delaware's "but for" rule of proximate cause in negligence cases). A determination of the proximate cause of a specific instance of a disease or medical condition must "rest upon the individualized findings and opinion of a trained physician." *Money v. Manville Corp. Asbestos Disease Comp. Tr. Fund,* 596 A.2d 1372, 1376 (Del. 1991). A plaintiff's bald assertion that he has a condition and that the condition was caused by a certain drug are insufficient.

Defendant argues that Plaintiff cannot establish proximate cause, as a matter of law, because he "has not produced an expert report addressing specific causation—i.e., that his use of generic risperidone caused his alleged gynecomastia or pus bumps." (D.I. 144 at 9). I agree. Plaintiff's claim is not supported by expert testimony that Risperdal proximately caused his condition. (D.I. 160 at 13 (arguing Plaintiff's proof is adequate based on expert testimony of general causation)). [2] Evidence of only "general causation" [3] is insufficient to establish a negligence claim under Delaware law. Thus, I will grant Defendant's motion for summary judgment.

B. Brand Name Liability for Plaintiff's Use of Generic Risperidone

Defendant also argues that it is entitled to summary judgment because Plaintiff never took the brand name drug that it manufactures, Risperdal. (D.I. 144 at 7-8). Rather, it is undisputed that Plaintiff took only generic risperidone. (*Id.* at 4-5). As I explain more fully in my simultaneously-entered summary judgment opinion in a related case, *Trower v. Janssen Pharms., Inc.*, Case No. 16-135-RGA (D. Del.), Delaware law does not support a claim against a brand name drug manufacturer for a plaintiff's use of a generic drug. I will grant Defendant's summary judgment motion for this additional reason.

C. Learned Intermediary Doctrine

***3** Defendant also argues that it is entitled to summary judgment because Plaintiff cannot establish that an additional warning would have changed Plaintiff's physician's decision to prescribe Risperdal. (D.I. 144 at 9). Plaintiff's evidence of the inadequacy of the Risperdal label is identical to the evidence presented in a related case, *Green v. Janssen Pharms., Inc.*, Case No. 15-401-RGA (D. Del.), and is similarly insufficient to establish the Risperdal label was inadequate as a matter of law. Moreover, it is undisputed that none of Plaintiff's physicians were deposed for this litigation. (D.I. 144 at 9). Thus, as I explain more fully in my simultaneously-entered summary judgment opinion in the *Green* case, Plaintiff cannot overcome Delaware's learned intermediary doctrine. I will grant Defendant's summary judgment motion for this additional reason.

IV. CONCLUSION

Plaintiff cannot establish a negligence cause of action under Delaware law because he has no evidence of proximate causation, did not consume Defendant's product, and cannot overcome Delaware's learned intermediary doctrine. Thus, I will grant Defendant's motion for summary judgment and enter judgment for Defendant. I will also dismiss Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan as moot. A separate order will be entered.

ORDER

For the reasons set forth in the accompanying Memorandum Opinion, **IT IS HEREBY ORDERED** that Defendant's Motion for Summary Judgment (D.I. 143) is **GRANTED** and Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan (D.I. 146) is **DISMISSED** as **MOOT.**

All Citations

Not Reported in Fed. Supp., 2019 WL 1567840

Footnotes

1 I use the brand name "Risperdal" to refer to the drug Plaintiff took. This is not meant to indicate whether Plaintiff took the brand name or a generic drug at any given time.

2 Plaintiff also does not have a diagnosis from a medical professional confirming that he does, in fact, have gynecomastia. (D.I. 160 at 6-7).

3 "General causation" addresses the question of whether a particular substance is capable of causing a particular harm. "Specific causation" addresses the related question of whether a particular substance caused a particular harm to a particular person.

2010 WL 2640170
Only the Westlaw citation is currently available.
United States District Court,
W.D. Arkansas,
El Dorado Division.

Kecia NEAL, Plaintiff
v.
TEVA PHARMACEUTICALS USA, INC.; Schwarz Pharma, Inc.; and Wyeth, Inc. d/b/a Wyeth, Defendants.

No. 09–CV–1027.
|
July 1, 2010.

Attorneys and Law Firms

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MEMORANDUM OPINION AND ORDER

HARRY F. BARNES, District Judge.

***1** Plaintiff Kecia Neal brought this products liability action against Defendants Wyeth, Inc. ("Wyeth"), Schwarz Pharma, Inc. ("Schwarz"), and Teva Pharmaceutical, Inc. ("Teva") claiming that she was injured by consuming metoclopramide, a prescription drug manufactured by the Defendants. The matter is now before the Court on a Motion for Summary Judgment filed on behalf of Defendants Wyeth and Schwarz (Doc. No. 21). Plaintiff responded to the motion. (Doc. No. 28). Defendants filed a reply to Plaintiff's response (Doc. No. 30), along with additional supplemental authority in support of the motion (Doc. Nos. 31 and 32). The Court finds the matter ripe for consideration.

BACKGROUND

Metoclopramide is a prescription drug approved by the FDA to treat gastroesophageal reflux disease. Metoclopramide is available in both name brand and generic forms. From approximately 1989 through late December 2001, Wyeth manufactured and distributed metoclopramide under the name brand Reglan®. In late December 2001, Schwarz acquired the rights to Reglan® from Wyeth. Thereafter, Schwarz manufactured and distributed Reglan® tablets until 2008. Since the mid–1980s, a number of companies, including Teva manufactured and distributed metoclopramide in its generic form.

Beginning in late 2005, Plaintiff Kecia Neal took metoclopramide for gastroparesis. She claims that her use of the drug caused her to develop tardive dyskinesia, a neurological movement disorder. Plaintiff concedes that she only ingested generic metoclopramide and she did not ingest any metoclopramide, either generic or name brand (Reglan®), that was manufactured or distributed by either Wyeth or Schwarz. Defendants Wyeth and Schwarz have moved for summary judgment in this case.

STANDARD OF REVIEW

The standard of review for summary judgment is well established. The Federal Rules of Civil Procedure provide that when a party moves for summary judgment;

> The judgment sought shall be rendered if the pleadings, the discovery and disclosure material on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to a judgment as a matter of law.

Fed.R.Civ.P. 56(c)(2); *Krenik v. County of LeSueur,* 47 F.3d 953 (8th Cir.1995). The Supreme Court has issued the following guidelines for trial courts to determine whether this standard has been satisfied:

> The inquiry performed is the threshold inquiry of determining whether there is a need for trial—whether, in other words, there are genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.

Anderson v. Liberty Lobby, Inc., 447 U.S. 242, 250 (1986). *See also Agristor Leasing v. Farrow,* 826 F.2d 732 (8th Cir.1987); *Niagara of Wisconsin Paper Corp. v. Paper Indus. Union–Management Pension Fund,* 800 F.2d 742, 746 (8th Cir.1986). A fact is material only when its resolution affects the outcome of the case. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. at 248. A dispute is genuine if the evidence is such that it could cause a reasonable jury to return a verdict for either party. *Id.* at 252.

***2** The Court must view the evidence and the inferences that may be reasonably drawn from the evidence in the light most favorable to the nonmoving party. *Enterprise Bank v. Magna Bank,* 92 F.3d 743, 747 (8th Cir.1996). The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Id.* The nonmoving party must then demonstrate the existence of specific facts in the record that create a genuine issue for trial. *Krenik v. County of LeSueur,* 47 F.3d at 957. A party opposing a properly supported motion for summary judgment may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. at 256.

DISCUSSION

Defendants Wyeth and Schwarz claim that they are entitled to judgment as a matter of law because the metoclopramide consumed by the Plaintiff was not manufactured or sold by either defendant. Plaintiff does not dispute that she never consumed any metoclopramide manufactured by either Wyeth or Schwarz. Rather, she contends that they are still liable for her injuries because they failed to adequately warm consumers of the dangers of using generic metoclopramide manufactured by other companies. Plaintiff brings her claims under Arkansas law for negligence, strict products liability, breach of warranties, express and implied, negligent and fraudulent misrepresentation, and gross negligence.

Although Plaintiff has brought this action under various state law theories for recovery, her claims are still product liability claims. *See* Ark.Code Ann. § 16–116–102(5) (defining "product liability action" to include "all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of any product."). The question

whether a plaintiff can maintain a products liability action in Arkansas against the name brand manufacture of a prescription drug when the consumer only ingested the generic form of the drug has been answered. In *Fields v. Wyeth, Inc., et al,* Judge Robert Dawson held that as a matter of law such an action can not be maintained in Arkansas. 613 F.Supp 2d 1056, 1058 (W.D.Ark.2009). The Court agrees with Judge Dawson's reasoning (and the weight of authority considering this issue [1]) and concludes that under Arkansas law a manufacturer of a brand name prescription drug may not be held liable for injuries arising from the use of another manufacturer's generic equivalent of the drug. Accordingly, since Plaintiff did not use any product manufactured by Wyeth or Schwarz, she can not maintain an action against either of these defendants.

CONCLUSION

For the foregoing reasons, the Court finds that the Motion for Summary Judgment filed by Defendants Wyeth, Inc. and Schwarz Pharma, Inc. should be and hereby is **granted.** All claims against these defendants are dismissed

***3** IT IS SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2010 WL 2640170

Footnotes

1 *See, e.g., Foster v. American Home Products Corp.,* 29 F.3d 165, 170 (4th Cir.1994); *Mensing v. Wyeth, Inc.,* 588 F.3d 603 (8th Cir.2009); *Calacicco v. Apotex, Inc.,* 432 F.Supp.2d 514 (E.D. Pa 2006); *Swicegood v. Pliva, Inc.,* 543 F.Supp.2d 1351 (N.D.Ga.2008); *LeBlanc, et al., v. Wyeth, Inc., et al.,* 2006 WL 2883030 (W.D.La. Oct. 5, 2006); *Pustejovsky v. Wyeth, Inc., et al.,* 2008 WL 1314902 (N.D. Tex. April 3, 2008); *Morris v. Wyeth, Inc., et al.,* 2008 WL 2677048 (W.D. Ky. June 30, 2008);

2015 WL 160696
Only the Westlaw citation is currently available.
United States District Court,
N.D. Mississippi,
Delta Division.

Diane TRUDDLE, Kaylyn Truddle, Ricky Carmichael, and Ricky Carmichael, Jr., all individually and as wrongful death beneficiaries of Eric Carmichael, deceased and on behalf of the Estate of Eric Carmichael, deceased, Plaintiffs

v.

WYETH, LLC; Schwarz Pharma, Inc.; and Alaven Pharmaceuticals, LLC, Defendants.

Civil Action No. 2:11–cv–00207–GHD–SAA.
|
Signed Jan. 12, 2015.

Attorneys and Law Firms

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Kaylyn Truddle, Coldwater, MS, pro se.

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MEMORANDUM OPINION GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

GLEN H. DAVIDSON, Senior District Judge.

***1** Presently before this Court in this *pro se* products liability case is a motion for summary judgment [79] filed by Defendants Alaven Pharmaceuticals, LLC and Wyeth, LLC. Upon due consideration of the motion and corresponding memorandum, letter response, and related authorities, the Court finds that the motion should be granted.

A. Factual and Procedural Background

This lawsuit arises from the tragic death of nineteen-year-old Eric Carmichael ("Mr.Carmichael"). The Plaintiffs allege the following facts in support of their claims: On June 9, 2008, Mr. Carmichael was admitted to the hospital with complaints of chest pain and gastritis. He was diagnosed with a gastric ulcer, gastritis, and esophagitis. His doctor prescribed Reglan/metoclopramide, relying on the information he had about the drug. Although Mr. Carmichael took the drug as directed and prescribed, he began suffering from side effects ranging from hallucinations, extreme restlessness (akathisia), feelings of craziness, and suicidal desires. On June 19, 2008, Mr. Carmichael secretly obtained a hand-gun and went to his room at his mother's house, purportedly to take a nap. His mother tried to get in touch with someone who could refer her son to a psychiatrist. Meanwhile, Mr. Carmichael moved a bookcase to block the door, sent a text to a friend stating that he was "now resting in peace," and took his own life with a self-inflicted gunshot wound to the right temple.

The Plaintiffs, Diane Truddle, Kaylyn Truddle, Ricky Carmichael, and Ricky Carmichael, Jr., individually and as wrongful death beneficiaries of Eric Carmichael, Deceased, bring this suit against the manufacturers of the drug, asserting claims for negligence, strict liability, breach of warranty, misrepresentation and fraud, and negligence *per se* based on the Defendants' alleged failure to warn of the risks of their products. [1] The Plaintiffs initially filed claims against the manufacturers of both the brand-name Reglan and the manufacturers of the generic metoclopramide. However, the Court dismissed the claims against the generic manufacturers as preempted by the United States Supreme Court's decision *PLIVA, Inc. v. Mensing,* ——U.S. ——, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011). The only remaining claims are those asserted against the manufacturers of the brand-name Reglan: Wyeth, LLC; Schwarz Pharma, Inc.; and Alaven Pharmaceuticals, LLC. Defendants Wyeth, LLC and Alaven Pharmaceuticals have now filed a motion for summary judgment on the remaining claims. [2]

B. Summary Judgment Standard

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett,* 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). *See* Fed.R.Civ.P. 56(a); *Johnston & Johnston v. Conseco Life Ins. Co.,* 732 F.3d 555, 561 (5th Cir.2013). The rule "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a sufficient showing to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp.,* 477 U.S. at 322, 106 S.Ct. 2548.

***2** The party moving for summary judgment bears the initial responsibility of informing the Court of the basis for its motion and identifying those portions of the record it believes demonstrate the absence of a genuine dispute of material fact. *See id.* at 323, 106 S.Ct. 2548. Under Rule 56(a), the burden then shifts to the nonmovant to "go beyond the pleadings and by ... affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.' " *Id.* at 324, 106 S.Ct. 2548; *Littlefield v. Forney Indep. Sch. Dist.,* 268 F.3d 275, 282 (5th Cir.2001); *Willis v. Roche Biomedical Labs., Inc.,* 61 F.3d 313, 315 (5th Cir.1995).

It is axiomatic that in ruling on a motion for summary judgment "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Tolan v. Cotton,* —— U.S. ——, ——, 134 S.Ct. 1861, 1863, 188 L.Ed.2d 895 (2014) (per curiam) (quoting *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)); *see, e.g., Ard v. Rushing,* —— F. App'x ——, 2014 WL 7356134, at *4 (5th Cir. Dec. 29, 2014) (per curiam) (quoting *United Fire & Cas. Co. v. Hixson Bros., Inc.,* 453 F.3d 283, 285 (5th Cir.2006) (on summary judgment, " '[w]e view the evidence in the light most favorable to the non-moving party' ")). The Court " 'resolve[s] factual controversies in favor of the nonmoving party, but only where there is an actual controversy, that is, when both parties have submitted evidence of contradictory facts.' " *Thomas v. Baldwin,* —— F. App'x ——, 2014 WL 7235529, at *1 (5th Cir. Dec. 19, 2014) (per curiam) (quoting *Antoine v. First Student, Inc.,* 713 F.3d 824, 830 (5th Cir.2013) (internal quotation marks and citation omitted)). "[T]he nonmoving party cannot defeat summary judgment with conclusory allegations, unsubstantiated assertions, or only a scintilla of evidence.' " *Id.* (quoting *Hathaway v. Bazany,* 507 F.3d 312, 319 (5th Cir.2007)).

"[A] 'judge's function' at summary judgment is not 'to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.' " *Cotton,* 134 S.Ct. at 1866 (quoting *Anderson,* 477 U.S. at 249, 106 S.Ct. 2505); *see Stewart v. Guzman,* 555 F. App'x 425, 430 (5th Cir.2014) (per curiam) (citing *Vaughn v. Woodforest Bank,* 665 F.3d 632, 635 (5th Cir.2011) (In ruling on a summary judgment motion, "[w]e neither engage in credibility determinations nor weigh the evidence.")). With the foregoing standard in mind, the Court turns to the issues before it.

C. Analysis and Discussion

In their motion for summary judgment, the Defendants argue that the remaining claims must be dismissed pursuant to the Fifth Circuit Court of Appeals' recent holding in *Lashley v. Pfizer, Inc.,* 750 F.3d 470 (5th Cir.2014), because the summary-judgment evidence shows that Mr. Carmichael ingested only the generic metoclopramide and never ingested the brand-name Reglan manufactured by the Defendants. The Plaintiffs submit a letter response seemingly indicating their understanding that the law is not on their side, but nonetheless imploring this Court to find in their favor.

***3** Although this Court affords greater latitude to *pro se* plaintiffs, realizing that such plaintiffs do not have the benefit of counsel, the Court cannot allow a case to proceed to trial based on "conclusory allegations, unsubstantiated assertions, or only a scintilla of evidence." *See Thomas,* 2014 WL 7235529, at *1 (quoting *Hathaway,* 507 F.3d at 319). *See also Bishop v. City of Galveston, Tex.,* —— F. App'x ——, 2014 WL 7235163, at *5 (5th Cir. Dec. 19, 2014) (per curiam) ("to defeat [a] motion for summary judgment, ... requires an evidentiary showing, not just allegations in a complaint"); *Russell v. Harrison,* 736 F.2d 283, 287 (5th Cir.1984) ("[A] plaintiff cannot establish a genuine issue of material fact by resting on the mere allegations of its pleadings."). The Plaintiffs' claims must be dismissed, because the summary-judgment proof before the Court demonstrates Mr. Carmichael took the generic metoclopramide, and the Plaintiffs have raised no genuine dispute of fact.

The Plaintiffs admit in their response to the Defendant's requests for admission that Mr. Carmichael ingested only the generic metoclopramide from June 14–19, 2008, four times daily. *See* Pls.' Resp. to Defs.' Reqs. Admiss. [79–6] ¶ 1. Walmart Pharmacy records attached to the Defendants' motion show that prescriptions were filled for the generic metoclopramide. *See* Walmart Pharmacy Rs. [79–4] at 3. The Plaintiffs state in their response to requests for admission that Mr. Carmichael "took Reglan June 12 around 9 PM, and on June 13[ ], 2008 at Baptist Hospital Desoto in Southaven. Refer to medical records." *See* Pls.' Resp. to Defs.' Reqs. Admiss. [79–6] ¶ 2. However, the Plaintiffs have not offered medical records substantiating this statement or otherwise provided proof that would raise a fact question on this issue. Although the Court recognizes the difficulty a *pro se* plaintiff faces in obtaining evidence to support his or her case, the Court cannot sustain a case past summary judgment if a plaintiff offers some form of proof in response. The only proof before the Court on this issue is the Defendants' attached affidavit of Ben Luk, the Director of Pharmacy Services at Baptist Memorial Hospital–Desoto, Inc. wherein he states:

> I currently serve as the Director of Pharmacy Services at Baptist Memorial Hospital–Desoto, Inc. ("BMH–Desoto"). I also held this same position in June 2008 when [Mr.] Carmichael was a patient at BMH–Desoto. As part of my job responsibilities, I oversee the procurement, storage[,] and distribution of pharmaceutical products throughout the BMH–Desoto hospital;
>
> The medical records of [Mr.] Carmichael reflect that following a physician order that [Mr.] Carmichael be administered the pharmaceutical metoclopramide, nursing staff administered a single 5[ ] mg dose of metoclopramide to [Mr.] Carmichael....

Luk Aff. [79–3] ¶¶ 2–3. Therefore, the summary-judgment proof demonstrates that Mr. Carmichael took metoclopramide, not Reglan. Mississippi products liability law does not impose liability in this factual situation, as explained below.

***4** The United States Food and Drug Administration (the "FDA") regulates the labeling of both brand-name drugs and generic drugs. *See* 21 C.F.R. § 314.50(c)(2)(i) (brand-name drugs); 21 C.F.R. § 314.94(a)(8) (generic drugs). "Before a manufacturer can market a new drug, the FDA must approve 'that it is safe and effective and that the proposed label is accurate and adequate.' " *Eckhardt v. Qualitest Pharms., Inc.,* 751 F.3d 674, 676 (5th Cir.2014) (quoting *Mensing,* 131 S.Ct. at 2574).

"The Mississippi Products Liability Act ('MPLA') applies 'in any action for damages caused by a product' and requires a plaintiff to prove that it was the defendant's product that caused the injury." *Lashley,* 750 F.3d at 476–77 (quoting MISS. CODE Ann. § 11–1–63); *see also Monsanto Co. v. Hall,* 912 So.2d 134, 136–37 (Miss.2005). Mississippi's products liability laws "shield the companies from liability for products they did not create." *Lashley,* 750 F.3d at 476 (citing MISS. CODE Ann. § 11–1–63). Applying this principle to cases such as this, "brand-name manufacturers are not liable for injuries caused by a plaintiff[']s ingestion of generic products." *Johnson v. Teva Pharms. USA, Inc.,* 758 F.3d 605, 616 n. 3 (5th Cir.2014). Further,

"a brand-name manufacturer does not owe a duty to consumers who use a generic version of the drug." *Eckhardt,* 751 F.3d at 681; *see Lashley,* 750 F.3d at 477 (citing *Moore ex rel. Moore v. Miss. Valley Gas Co.,* 863 So.2d 43, 46 (Miss.2003) ("[I]t is incumbent upon the plaintiff in any products liability action to show that the defendant's product was the cause of the plaintiff's injuries.")). The Fifth Circuit's holdings are consistent with other circuit courts of appeals confronted with the issue and applying various states' laws. *See Eckardt,* 751 F.3d at 681–82 (citing *Guarino v. Wyeth, LLC,* 719 F.3d 1245, 1252 (11th Cir.2013) (same under Florida law); *Schrock v. Wyeth, Inc.,* 727 F.3d 1273, 1282–1285 (10th Cir.2013) (same under Oklahoma law); *Strayhom v. Wyeth Pharm ., Inc.,* 737 F.3d 378, 401–06 (6th Cir.2013) (same under Tennessee law); *Bell v. Pfizer, Inc.,* 716 F.3d 1087, 1092–1093 (8th Cir.2013) (same under Arkansas law); *Smith v. Wyeth, Inc.,* 657 F .3d 420, 423–24 (6th Cir.2011) (same under Kentucky law), *cert. denied,* —— U.S. ——, 132 S.Ct. 2103, 182 L.Ed.2d 868 (2012); *Foster v. Am. Home Prods. Corp.,* 29 F.3d 165, 170–71 (4th Cir.1994) (same under Maryland law)).

Therefore, based on Fifth Circuit precedent and Mississippi law, "because [Mr. Carmichael] did not ingest the brand manufacturers' products, these [D]efendants have no common-law duty to [the Plaintiffs]." *See id.* at 476. Therefore, the Plaintiffs have no possibility of prevailing on their products liability, negligence, and misrepresentation claims against the brand-name Defendants and summary judgment is proper on these claims.

Insofar as the Plaintiffs have alleged a fraud claim against the Defendants, the Plaintiffs fail to allege sufficient facts for the claim to survive summary judgment. Fraud claims are subject to the heightened pleading standards of Rule 9(b) of the Federal Rules of Civil Procedure, which requires a party to plead "the circumstances constituting fraud ... with particularity." Fed.R.Civ.P. 9(b). "Put simply, Rule 9(b) requires the who, what, when, where, and how to be laid out." *Benchmark Elecs., Inc. v. J.M. Huber Corp.,* 343 F.3d 719, 724 (5th Cir.2003) (internal quotation marks omitted). In their amended complaint, the Plaintiffs allege that the Defendants "misrepresented to the FDA, [Mr. Carmichael], and the health care industry the safety and effectiveness of Reglan/metoclopramide and/or fraudulently, intentionally [,] and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Reglan/ metoclopramide." *See* Pls.' Am. Compl. [4] ¶ 127. These allegations, without further factual and evidentiary support, are not sufficient to sustain the claim past summary judgment. Therefore, summary judgment is proper on this claim, as well.

D. Conclusion

***5** The Court is very sympathetic and saddened by the set of circumstances presented in the case *sub judice,* but is powerless to sustain the claims against the Defendants. In sum, the Court finds that all remaining claims should be dismissed, because no genuine dispute of fact exists that would preclude summary judgment on the claims. Judgment is proper as a matter of law.

A separate order in accordance with this opinion shall issue this day.

All Citations

Not Reported in F.Supp.3d, 2015 WL 160696

Footnotes

1 The Plaintiffs initially brought this action in the Circuit Court of Desoto County with the assistance of counsel. Subsequently, the Plaintiffs' counsel filed a motion to withdraw, which was granted in state court. The case was then removed to this Court. The Plaintiffs proceed *pro se.*

2 Apparently, the Defendant Schwarz Pharma, Inc. was never served with a summons and complaint. *See* Clerk's Notices of Incomplete Process [36, 46, & 63].

2012 WL 12991011
Only the Westlaw citation is currently available.
United States District Court, E.D. Louisiana.

Michael MATHERNE
v.
BAYER HEALTHCARE PHARMACEUTICALS, INC., et al.

CIVIL ACTION NO. 11-2188
|
Signed 11/01/2012
|
Filed 11/02/2012

Attorneys and Law Firms

Michael Matherne, Des Allemands, LA, pro se.

SECTION "H" (5)

ORDER AND REASONS

JANE TRICHE MILAZZO, UNITED STATES DISTRICT JUDGE

***1** Before the Court are Defendants Watson Pharmaceuticals, Inc. and Mylan Pharmaceuticals, Inc.'s Motion for Judgment on the Pleadings (R. Docs. 40, 46) and Defendant Bayer Healthcare Pharmaceuticals, Inc.'s Motion for Summary Judgment (R. Doc. 56). For the following reasons, Defendants Watson Pharmaceuticals, Inc. and Mylan Pharmaceuticals, Inc.'s Motion for Judgment on the Pleadings is DENIED and Bayer Healthcare Pharmaceuticals, Inc.'s Motion for Summary Judgment is GRANTED.

BACKGROUND

Plaintiff Michael Matherne ("Matherne") alleges that he suffered physical injuries and damages upon ingesting ciprofloxacin, a drug prescribed by his doctors on two separate occasions in 2010. (R. Doc. 1.) On August 31, 2011, Matherne filed his Complaint under the Louisiana Products Liability Act, breach of warranty of redhibition, and common law theories of breach of implied warranty, unjust enrichment, and negligence. Matherne's Complaint named three manufacturers of ciprofloxacin —Bayer Healthcare Pharmaceuticals, Inc. ("Bayer"), Merck Sharp & Dohme Corp. ("Merck"), and Apotex, Inc. ("Apotex") —as Defendants. (*Id.*) Subsequently, Matherne amended his Complaint wherein he dismissed Defendants Apotex and Merck and substituted Watson Pharmaceuticals, Inc. ("Watson") and Mylan Pharmaceuticals, Inc. ("Mylan"). (R. Doc. 34.) Bayer Healthcare is the remaining third Defendant and is a manufacturer of Cipro®, the brand-name equivalent of ciprofloxacin.

On March 15, 2012, Watson filed a Motion for Judgment on the Pleadings. (Doc. 40.) On March 26, 2012, Mylan filed a Motion adopting Watson's arguments. (Doc. 46.) On April 22, 2012, Bayer filed a Motion for Summary Judgment. (Doc. 56.) Plaintiff opposed these motions on May 30, 2012. (Docs. 61-62.) A submission date of August 1, 2012 was set for all three motions.

LAW AND ANALYSIS

Defendants Watson and Mylan ("Generic Defendants") request dismissal of the Plaintiff's Complaint on the basis that it fails to state a claim to relief that is plausible on its face, and therefore, judgment as a matter of law is appropriate. The Court finds, however, that the Plaintiff has plead enough facts in his Complaint to survive a motion under Rule 12(c) of the Federal Rules of Civil Procedure. Therefore, Generic Defendants' Motion for Judgment on the Pleadings is denied.

As to Defendant Bayer and its request for summary judgment, the Court finds that Bayer has met its burden of showing that there is no genuine issue of material fact while Matherne's response failed to provide evidence to support his claims. Accordingly, Bayer's Motion for Summary Judgment is granted.

I. *Generic Defendants' Motion for Judgment on the Pleadings*

A. Legal Standard

Motions to dismiss filed after an answer are treated as motions for judgment on the pleadings under Rule 12(c). *See* Fed. R. Civ. P. 12(c); *see also Jebaco, Inc. v. Harrah's Operating Co., Inc.,* 587 F.3d 314, 317 n.5 (5th Cir. 2009). The standard for deciding a Rule 12(c) motion, however, is the same as the standard for deciding a motion under Rule 12(b)(6). *Gentilello v. Rege*, 627 F.3d 540, 543-44 (5th Cir. 2010). To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must plead enough facts "to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 547 (2007)). A claim is "plausible on its face" when the pleaded facts allow the court to "[d]raw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S.Ct. at 1949. A court must accept the complaint's factual allegations as true and must "draw all reasonable inferences in the plaintiff's favor." *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 232 (5th Cir. 2009). The Court need not, however, accept as true legal conclusions couched as factual allegations. *Iqbal*, 129 S.Ct. at 1949–50.

***2** To be legally sufficient, a complaint must establish more than a "sheer possibility" that the plaintiff's claims are true. *Id.* at 149. The complaint must contain enough factual allegations to raise a reasonable expectation that discovery will reveal evidence of each element of the plaintiffs' claim. *Lormand*, 565 F.3d at 255–57. If it is apparent from the face of the complaint that an insurmountable bar to relief exists, and the plaintiff is not entitled to relief, the court must dismiss the claim. *Jones v. Bock*, 549 U.S. 199, 215 (2007).

B. Analysis

The Court finds that Generic Defendants have failed to meet the pleading standard applicable to their motion; consequently, their Motion for Judgment on the Pleadings is denied.

The Plaintiff's Complaint alleges that the Defendants failed to comply with state and federal laws in the manufacture, design, labeling, and sale of ciprofloxacin. (R. Doc. 1.) Matherne avers that the Food and Drug Administration ("FDA") determined ciprofloxacin requires a Boxed Warning [1] to caution its consumers of the increased risk of tendinitis and tendon rupture, but such warnings did not accompany the ciprofloxacin he ingested. As such, Matherne argues that the drug is unreasonably dangerous, and the Defendants failed to conform to federal and state requirements for providing adequate labels and warnings to consumers. (*Id.*)

Generic Defendants assert that in the state of Louisiana, the Louisiana Products Liability Act ("LPLA") sets forth the exclusive theories of liability against manufacturers, thereby precluding Matherne's non-LPLA claims. (R. Doc. 40-1.) Additionally, Generic Defendants argue that all failure-to-warn claims against generic drug manufacturers are preempted by federal regulations applicable to generic drug manufacturers. (*Id.*) They allege that federal regulations promulgated by the FDA require generic drug manufacturers to provide warning labels for their prescription products that are substantively identical to the

warning label of the brand-name drug. (*Id.*) As a result, they contend that generic drug manufacturers, such as themselves, are prohibited from including new or additional warnings that are inconsistent with those of the brand-name drug. (*Id.*) They argue that all state-law claims are preempted by the FDA's "sameness" mandate, which prevents generic manufacturers from substantively changing the labels from those of its brand-name counterpart. (*Id.*) Thus, they conclude that dismissal is proper because under federal law, generic drug manufacturers are prohibited from unilaterally strengthening their warning labels, and cannot send letters to physicians providing additional warnings. (*Id.*)

In regards to the non-LPLA claims, the Court finds that Matherne's breach of warranty of rehibition, breach of implied warranty, unjust enrichment, and negligence claims are barred because the LPLA provides the exclusive theories of recovery for plaintiffs suing product manufacturers in the state of Louisiana. *See* La.Rev.Stat.Ann. § 9:2800.52 (West 2012). The LPLA holds any manufacturer liable for damages for producing an unreasonably dangerous product, including instances where a manufacturer fails to provide sufficient labels that warn consumers of the product's associated risks. *See* La.Rev.Stat.Ann. § 9:2800.54(B)(1)-(4) (West 2012). The Court concludes at the outset that the LPLA controls this matter and all of Plaintiff's claims must be examined in that context. *See* La.Rev.Stat.Ann. § 9:2800.51 *et seq.*; *see also Sheridan v. Merck & Co., Inc.*, No. Civ.A. 02–2581, 2003 WL 22902622, at *2 (E.D. La. Dec. 8, 2003). Therefore, Matherne's non-LPLA claims are dismissed.

***3** This Court further finds that Generic Defendants preemption argument is correct. In *PLIVA Inc. v. Mensing*, 131 S.Ct. 2567 (2011), the plaintiffs claimed that generic manufacturers of a drug failed to adequately warn physicians of all the risks associated with long-term use of the medication. The Supreme Court of the United States directly addressed the interplay between the law in Louisiana which provides that "a manufacturer's duty to warn includes a duty to provide adequate instructions for safe use of a product," *Mensing*, 131 S.Ct. at 2573 (quoting *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 269–270 (5th Cir. 2002)), and the federal drug regulations applicable to generic drug manufactures which requires their labeling be the same as the name-brand drug's labeling. *Id.* at 2575 (citing 57 Fed.Reg. 17961 (1992)). Indeed, the Court found that the federal regulations directly conflicted with the LPLA's requirement that drug manufacturers provide adequate warning labels. *Id.* at 2577. The Court reasoned that when it is impossible to comply with both the state and the federal law, the state law is preempted, and ultimately dismissed the plaintiff's LPLA claims. *Id.* In the end, federal regulations demand that "generic drug labels be the same at all times as the corresponding brand-name drug labels." *Id.* at 2578. As such, a generic manufacturer, including Generic Defendants, are prevented from unilaterally adding or otherwise changing the labels from those of its brand-name counterpart. *See Id.* at 2575.

In this case, Matherne claims that the Generic Defendants' labels failed to adequately warn physicians of the increased risk of tendinitis and tendon rupture associated with the use of ciprofloxacin. Although the state requirements are preempted by the federal regulation, as articulated by the Generic Defendants, the federal "sameness" requirement does not preclude Plaintiff from claiming that the generic drug manufacturer's label was inadequate because it *differed* from the brand-name manufacturer's label. By requesting this Court to dismiss Matherne's Complaint under Rule 12(c), the Generic Defendants are essentially asking the Court to assume that their generic drugs' labels were the same as the brand-name drug's label, or stated differently, that they were in compliance with the federal regulations. Since the possibility exists that the warning labels provided by the Generic Defendants failed to conform to federal law, as declared by Matherne in his Complaint, and because the Generic Defendants failed to provide evidence showing otherwise, dismissal pursuant to a motion for judgment on the pleadings is not appropriate at this time.

In conclusion, the Plaintiff's Complaint alleges that the Generic Defendants were not in compliance with federal and state labeling requirements. Reading this assertion in light most favorable to the *pro se* Plaintiff, the Court finds that the Complaint states a claim to relief that is plausible on its face. Generic Defendants imparted the Court with ample evidence to support their argument that the LPLA sets forth exclusive theories of recovery, and federal law preempts these claims; however, the Court finds that Generic Defendants have failed to provide evidence that their labels were the same as the brand-name counterpart as required by federal law. As such, Generic Defendants' Motion for Judgment on the Pleadings is denied.

II. *Defendant Bayer's Motion for Summary Judgment*

A. Legal Standard

Summary judgment is appropriate "[i]f the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c) (2012). A genuine issue of fact exists only "[i]f the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

In determining whether the movant is entitled to summary judgment, the Court views facts in the light most favorable to the nonmovant and draws all reasonable inferences in his favor. *Coleman v. Houston Indep. Sch. Dist.*, 113 F.3d 528 (5th Cir. 1997). "If the moving party meets the initial burden of showing that there is no genuine issue of material fact, the burden shifts to the non-moving party to produce evidence or designate specific facts showing the existence of a genuine issue for trial." *Engstrom v. First Nat'l Bank of Eagle Lake*, 47 F.3d 1459, 1462 (5th Cir. 1995). Summary judgment is appropriate if the non-movant "[f]ails to make a showing sufficient to establish the existence of an element essential to that party's case...." *CelotexCorp. v. Catrett*, 477 U.S. 317,324 (1986). "In response to a properly supported motion for summary judgment, the nonmovant must identify specific evidence in the record and articulate the manner in which that evidence supports that party's claim, and such evidence must be sufficient to sustain a finding in favor of the nonmovant on all issues as to which the nonmovant would bear the burden of proof at trial." *John v. Deep E. Tex. Reg. Narcotics Trafficking Task Force*, 379 F.3d 293,301 (5th Cir. 2004) (internal citations omitted). "We do not ... in the absence of any proof, assume that the nonmoving party could or would prove the necessary facts." *Badon v. RJ R Nabisco, Inc.*, 224 F.3d 382, 394 (5th Cir. 2000) (quoting *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994)). Additionally, "[t]he mere argued existence of a factual dispute will not defeat an otherwise properly supported motion." *Boudreaux v. Banctec, Inc.*, 366 F.Supp.2d 425, 430 (E.D. La. 2005)

B. Analysis

***4** The Court finds that Bayer successfully demonstrated the absence of a genuine issue of material fact and is therefore entitled to judgment as a matter of law.

Bayer argues that it is not the proper defendant for the Plaintiff's suit. Bayer alleges that undisputed facts establish that Matherne ingested a generic form of ciprofloxacin. (R. Doc. 56.) Thus, Bayer concludes that as a brand-name manufacturer of Cipro®, it cannot possibly be considered a manufacturer of the drug ingested by Matherne. Because a manufacturer does not owe a duty to a consumer of a product manufactured by another company, Bayer argues that Matherne's claims against it must be dismissed. (R. Doc. 56-2.)

The relevant LPLA provision states as follows: "The manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." La.Rev.Stat.Ann. § 9:2800.54. One way a product is deemed unreasonably dangerous is by showing the manufacturer of the product failed to provide an adequate warning. *Id.*; *Morris v. Wyeth*, No. 09-0854, 2009 WL 4064103, *2 (W.D. La. Nov. 23, 2009). The statute makes clear that a manufacturer is liable for any unreasonably dangerous product it manufactures. It does not, however, state that a manufacturer who creates a product that is substantially similar to another manufacturer's product in its ingredients, safety, efficacy, and labeling are liable for the other product's defects. *See Mensing,* 131 S.Ct. at 2574 n.2 (explaining that a "generic drug" is a drug designed to be a copy of the brand-name drug and thus "identical in active ingredients, safety, and efficacy.")

To recover damages under the LPLA, a plaintiff must first establish that "the defendant is the manufacturer of the product." *Matherne v. Poutrait-Morin/Zefal-Christophe, Todson, Inc.*, 868 So. 2d 114, 119 (La. App. 2003). Under the LPLA, Matherne can only assert a claim against the manufacturer of the product he consumed, *See* La.Rev.Stat.Ann. § 9:2800.54, which was *generic* ciprofloaxin medication identifiable by the corresponding NDC numbers. Bayer attaches an affidavit of the company's Director of Quality Assurance (R. Doc. 56-7) and copies of Matherne's ciprofloxacin prescriptions (R. Doc. 56-6), which together, prove that the National Drug Code ("NDC") of its Cipro® product differs from those prescribed to Matherne. Thus, the Court finds that Bayer has provided sufficient evidence to show that it did not manufacture the product at issue. As evidenced

by the affidavit and copies of Matherne's ciprofloaxin prescriptions, Bayer is a brand-name manufacturer of Cipro® and its product's NDC numbers do not match those of the product at issue. Because Matherne has failed to show that the product he ingested was manufactured by Bayer, Matherne's claims against Bayer must be dismissed.

CONCLUSION

***5** For the aforementioned reasons, Defendants Watson Pharmaceuticals, Inc. and Mylan Pharmaceuticals, Inc.'s Motion for Judgment on the Pleadings (R. Docs. 40, 46) are **DENIED** and Bayer Healthcare Pharmaceuticals, Inc.'s Motion for Summary Judgment (R. Doc. 56) is **GRANTED**.

All Citations

Not Reported in Fed. Supp., 2012 WL 12991011

Footnotes

1 A boxed warning is defined as "an alert to medical practitioners about potentially serious adverse drug reactions, contraindications, or other special problems with a given drug, contained in a ruled box at a site specified within the label format by the FDA." *PDR Medical Dictionary* 2145 (3d ed. 2006).

2012 WL 2401776 (N.J.Super.) (Trial Order)
Superior Court of New Jersey.
Atlantic County

Ruby Edna COUNDOURIS,
v.
WYETH, et al.;
Barbara Danziger,
v.
Wyeth, et al.;
Basil and Emily Downer,
v.
Wyeth, et al.;
Kamile Drake and Atay Kural,
v.
Wyeth, et al.;
Joyce M. Lorber,
v.
Wyeth, et al.;
Craig G. Lynn,
v.
Wyeth, et al.;
Catherine R. Monroe,
v.
Wyeth, et al.;
Diane and Arnold Riback,
v.
Wyeth, et al.

Nos. ATL-L-1940-10, ATL-L-4513-10, ATL-L-0843-11, ATL-L-0262-11, ATL-L-1973-11, ATL-L-6357-10, ATL-L-0257-11, ATL-L-1927-11.
June 26, 2012.

Brand Manufacturers' Joint Motion to Dismiss

Ezra D. Rosenberg, Esq., Dechert LLP - Attorney for Defendants Wyeth LLC, Wyeth Pharmaceuticals, Inc., and Wyeth Holdings Corporation.

Tracy McDevitt Hagan, Esq., Reilly, Janiczek & McDevitt, P.C. - Attorney for Defendants Alaven Pharmaceutical LLC, and Schwarz Pharma, Inc.

Theodore Oshman, Esq., Oshman & Mirisola, LLP - Attorney for Plaintiffs.

Carol E. Higbee, P.J.Cv.

Having carefully reviewed the papers submitted and any response received, I have ruled on the above Motion as follows:

Defendants Wyeth LLC, Wyeth Pharmaceuticals Inc., and Wyeth Holdings Corporation (together, "Wyeth"), Schwarz Pharma, Inc. ("Schwarz"), and Alaven Pharmaceutical LLC ("Alaven") (collectively, "Brand Defendants") filed this Motion seeking to dismiss the actions brought against them by Plaintiffs Ruby Coundouris, Barbara Danziger, Basil and Emily Downer, Kamile Drake and Atay Kural, Joyce Lorber, Craig Lynn, Catherine Monroe, and Diane and Arnold Riback (collectively, "Plaintiffs"). Plaintiffs filed an opposition, and Brand Defendants filed a reply. Oral argument was held.

I. Background

Metoclopramide is a prescription drug approved by the FDA to treat gastroesophageal reflux disease and diabetic gastroparesis. Metoclopramide is available in both brand-name (Reglan®) and generic formulations.

The Brand Defendants manufactured and distributed Reglan®. Wyeth manufactured and distributed Reglan® tablets until late 2001, at which time it sold rights and responsibilities concerning Reglan® to Schwarz. Thereafter, Schwarz manufactured and distributed Reglan® tablets until 2008. Alaven purchased the right to Reglan® tablets from Schwarz in 2008 and sold Reglan® tablets until June 2011.

Plaintiffs never took Reglan®, but instead ingested generic metoclopramide manufactured by various companies other than the Brand Defendants.[1] Plaintiffs assert claims against the Brand Defendants for conscious misrepresentation, negligent misrepresentation, and negligence. Plaintiffs Lorber and Lynn also allege design and manufacturing defect claims under the PLA. Breach of express warranty claims have also been brought by some of the Plaintiffs against some or all Brand Defendants.

II. Legal Standard

Pursuant to *Rule* 4;6-2(e), a defendant may move to strike all or part of a complaint for "failure to state a claim upon which relief can be granted." Such a motion entails scrutiny of the complaint to determine whether any viable cause of actions exists. "[T]he test for determining the adequacy of a pleading [is] whether a cause of action is 'suggested' by the facts At this preliminary stage of the litigation the Court is not concerned with the ability of plaintiffs to prove the allegation contained in the complaint." *Printing Mart-Morristown v. Sharp Elec. Corp.,* 116 *N.J.* 739, 746 (1989) (quoting *Velantzas v. Colgate-Palmolive Co.,* 109 N.J. 189, 192 (1988)).

III. Discussion

The parties have agreed that New Jersey law applies for purposes of the resolution of this motion only.

In support of their Motion to Dismiss, Brand Defendants argue that the New Jersey Products Liability Act ("PLA") governs Plaintiffs' claims, and that pursuant to the PLA and New Jersey case law, manufacturers of a brand-name drug may not be held liable for injuries caused by a plaintiff's use of a generic drug manufactured by another company.

In opposition, Plaintiffs argue that their claims against Brand Defendants are not products liability claims governed by the PLA, but are instead negligence claims governed by New Jersey common law. Plaintiffs contend that the Brand Defendants owed a duty to those ingesting generic metoclopramide to exercise reasonable care in either disseminating accurate, non-misleading information about metoclopramide or adequately warning doctors and patients as to the risk of the drug.

Under the PLA, a "product liability action" is defined as "*any* claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim." *N.J.S.A.* § 2A:58C-l(b)(3) (emphasis added). The PLA defines "harm" to include "personal physical illness, injury or death"; "pain and suffering, mental anguish or emotional harm"; and "any loss of consortium or other services or other loss deriving from any type of harm described." *N.J.S.A.* §2A:58C-l(b)(2).

As the New Jersey Supreme Court has explained, "[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *Sinclair v. Merck & Co., Inc.,* 195 N.J. 51, 66 (2008); *In re Lead Paint Litig.,* 191 *N.J.* 405, 436-37 (2007).

The Court finds that Plaintiffs' cases are products liability actions governed by the PLA. The central focus of Plaintiffs' claims is that the Brand Defendants were aware of dangers associated with metoclopromide, and either failed to disseminate accurate information about the drug, or failed to adequately warn as to the dangers of its usage. Such a classic articulation of tort law duties falls squarely within the theories included in the PLA. See *In re Lead Paint Litig., supra,* 191 *N.J.* at 437 (finding that the duties to warn of, or make safe, were squarely within the theories included in the PLA). In light of the clear intention of our Legislature to include all such claims within the scope of the PLA, the Court finds no ground on which to conclude that the claims being raised by Plaintiff's, regarding a prescription drug used by patients, were excluded from the scope of the PLA.

Having concluded that the Plaintiffs' claims are governed by the PLA, the Court finds that Plaintiffs' action must fail because they did not ingest a product made or sold by the Brand Defendants. In New Jersey, "it is well-settled that in products-liability litigation, [a plaintiff] must demonstrate that his or her injuries were caused by...defendant's...product." *Gannon v. Am. Home Products. Inc.,* 414 *N.J. Super.* 507, 525 (App. Div. 2010) (quoting *Vassallo v. Am. Coding & Marking Ink Co.,* 345 *N.J. Super.* 207, 214 (1993)) (internal quotations omitted). "[P]roof of causation-in-fact is ordinarily an indispensible ingredient of a *prima facie case...*" *Ibid.* (quoting *Shackil v. Lederle Labs.,* 116 N.J. 155,163 (1989); *see also Namm v. Charles E. Frosst & Co.,* 178 *N.J. Super.* 19, 27 (App. Div. 1981) ("It is a fundamental principle of products liability law that a plaintiff must prove, as an essential element of his case, that the defendant manufacturer actually made the particular product which caused injury.")

This Court's decision in *Rossi v. Hoffman-LaRoche,* No. ATL-L-690-05 (N.J. Super. Ct. Jan 3. 2007), is instructive. In *Rossi,* the plaintiff brought suit against the brand-name manufacturer, Hoffman-LaRoche, Inc., for misrepresentations, claiming damages purportedly caused by the plaintiff's ingestion of a generic version (mefloquine) of the brand-name manufacturer's product (Lariam®). This Court declined to create a duty on the part of the name-brand manufacturer to the consumers of a generic drug and dismissed the plaintiff's action against Hoffman-LaRoche. In reaching its decision, this Court noted that there was "no evidence" that "the New Jersey legislature intended for prescription drug liability to extend to the name-brand manufacturer when the alleged victim ingested a generic equivalent manufactured and sold by another company." In addition, this Court found that the PLA reflected the Legislature's intent to limit liability to specific parties - namely the manufacturer or seller of a product.

Consistent with New Jersey precedent, other trial courts have reached a similar conclusion when confronting this issue. See *Sloan v. Wyeth,* No. MRS-L-1183-04 (N.J. Super. Ct. Oct. 13, 2004) (granting summary judgment against a negligent misrepresentation claim brought by plaintiffs suing drug manufacturer for harm caused by ingestion of another company's generic metoclopramide); *Westerlund v. Wyeth, Inc.,* No. MID-02174-05, 2008 WL 5592753, at *3 (N.J. Super. Ct. Oct. 20, 2008) (declining to extend liability against drug manufacturer where plaintiff did not use their product).

The United States Supreme Court's decision in *Pliva v. Mensing,* 131 *S. Ct.* 2567, 180 *L. Ed.* 2d 580 (2011) does not change New Jersey law. In *Mensing,* the Supreme Court found that federal regulations applicable to generic manufacturers preempted state law failure to warn claims against those manufacturers. The practical effect of *Mensing*'s holding is that generic manufacturers who comply with the FDA requirement that they mimic the brand-name manufacturers' warning labels cannot be held liable under state tort law for failure to warn. However, *Mensing* did not address or impact the issue currently before this Court -- namely, whether a brand-name manufacturer owes a duty to a patient who ingested a drug that the brand-name manufacturer did not make or sell. Because *Mensing* did not alter New Jersey law, the PLA and case law continue to govern.

To be sure, the Court recognizes cases from other jurisdictions, such as *Conte v. Wyeth, Inc.,* 85 *Cal. Rptr.* 3d 299 (Ct. App. 2008), which have extended a brand-name manufacturer's duty to warn to patients whose doctors rely on the brand-name manufacturer's product information when prescribing metoclopramide, whether the prescription is written for or filled with Reglan or its generic equivalent. Nonetheless, this Court is bound by the statutory and case law of the State of New Jersey.

Our courts have made clear that an essential element of a plaintiff's prima facie products liability action case is proof that the manufacturer actually produced the product which gave rise to the plaintiff's injury.

Where Plaintiffs never ingested metoclopramide manufactured or sold by the Brand Defendants, they are unable to establish an essential element of their *prima facie* case under New Jersey law, and their claims against the Brand Defendants must be dismissed.

In these cases, all claims against Wyeth are dismissed, with the exception of Craig Lynn and Barbara Danziger, against whom only Counts I, II, and VII are dismissed. All claims against Schwarz are dismissed, with the exception of Craig Lynn. All claims against Alaven are dismissed, with the exception of Barbara Danziger.

<<signature>>

CAROL E. HIGBEE, P.J.Cv.

Footnotes

1 Plaintiffs all ingested generic metoclopramide. However, Craig Lynn alleges that he used brand-name Reglan® manufactured by both Wyeth and Schwarz, and some generic metoclopramide manufactured by a division of Wyeth, ESI Lederle ("Lederle"). Barbara Danziger admits that she ingested only generic metoclopramide but alleges that some of the generic product was manufactured by Lederle.
Brand Defendants have jointly moved to dismiss all claims that are asserted against them based on Plaintiffs' theory that the Brand Defendants are liable because they manufactured Reglan®, even though they did not manufacture the generic metoclopramide that Plaintiffs ingested.
Brand Defendants have adopted this motion with the following qualifications: (1) Wyeth moves to dismiss all claims of Plaintiffs except Craig Lynn and Barbara Danziger, against whom Wyeth moves to dismiss only Counts I, II, and VII; (2) Schwarz moves to dismiss the claims of all Plaintiffs except Craig Lynn; (3) Alaven moves to dismiss all claims of all Plaintiffs except Barbara Danziger, who has agreed to dismiss her claims against Alaven based on the fact that she stopped taking metoclopramide before Alaven acquired any rights associated with Reglan®.

2018 WL 5017045 (N.Y.Sup.), 2018 N.Y. Slip Op. 32645(U) (Trial Order)
Supreme Court of New York.
New York County

**1 Zayre PRESTON, Plaintiff,

v.

JANSSEN PHARMACEUTICALS, INC, Janssen Ortho, LLC, Janssen Phrms, Glenmark Pharmaceuticals, Inc., Glenmark Pharmaceuticals, USA Inc., Glemark Generics Inc., USA, Glenmark Generics and Dr. Raihana Khorasanee, M.D., Defendants.

No. 158570/17.
October 12, 2018.

Trial Order

Joan A. Madden, J.

*1 In this action asserting claims for medical malpractice, negligence and products liability, defendants Glenmark Pharmaceuticals, Inc., Glenmark Pharmaceuticals Inc., USA, and Glenmark Generics (together "Glenmark") move to dismiss the claims against them on the grounds that they are preempted by federal law and for failure to state a cause of action (motion seq no. 002). Defendants Janssen Pharmaceuticals, Inc., Janssen Ortho, LLC and Janssen Phrms (together "Janssen") separately move to dismiss the claims against them, asserting that they cannot be held liable to plaintiff as its product was not responsible for plaintiff's alleged injuries (motion seq. no. 003). [1] Plaintiff opposes both motions.

**2 *Background* [2]

In this action, plaintiff alleges that she lost most of the vision in both eyes as a result of being prescribed "Topamax and/or Topiramate" by defendant Dr. Raihana Khorasannee ("Dr. Khorasannee"), on or about April 16, 2014, [3] while being treated for a psychiatric condition (Complaint ¶ 11, Plaintiff's Aff. ¶ 1). Plaintiff alleges that "from about April 28, 2015 to May 1, 2015, she began experiencing pain to the left eye... [and thereafter] was diagnosed with uveitis and other eye disorders directly caused by consumption of Topamax and/or Topiramate" (Complaint ¶'s 12, 13). Plaintiff did not know that the uveitis and other eye disorders were caused by the medication until May 24, 2017, after she consulted with her attorney (Plaintiff's Aff ¶ 4). The pharmacy records submitted by plaintiff show that she was prescribed Topiramate between April 16, 2014 and March 22, 2017.

*2 The complaint asserts claims for strict product liability, breach of implied warranty, breach of express warranty, negligence, and violation of General Business Law § 349 and § 350, **3 against Janssen and Glenmark, and for medical malpractice and lack of informed consent against Dr. Khorasanee, who has separately moved to dismiss the claims against her.

Topamax is a brand name topiramate drug manufactured by Janssen that is indicated for the treatment of certain types of seizures, as well as for migraine prevention. The Food and Drug Administration ("FDA") approved Topamax for sale by Janssen on December 24, 1996, and granted Janssen market exclusivity for thirteen years. In 2001, Janssen issued a letter to consumers stating that it had strengthened the drug's warnings and precautions regarding an ocular syndrome reportedly experienced by users-namely cases of secondary angle closure glaucoma characterized by ocular pain, acute myopia, and increased intraocular pressure. The strengthened warning included a warning that if left untreated, serious injury including permanent vision loss could occur. This warning has been displayed by Janssen since 2001.

In 2009, after Janssen's patent protection expired, the FDA approved the sale of generic versions of Topamax marketed as Topiramate. Of relevance here, on March 27, 2009, the FDA approved the sale of the generic Topiramate by Glenmark. Topiramate has the same active ingredients, strength, dosage form, and route of administration as the brand-name FDA-approved Topamax.

Janssen's Motion

Janssen moves to dismiss the complaint against it, arguing that it has never manufactured, marketed or sold generic Topiramate, nor does plaintiff allege that Janssen ever did, and thus it cannot be held liable to plaintiff for any injuries she sustained as a result ingesting generic Topiramate. Janssen further argues that applicable New York statutes mandate that absent an explicit instruction from the prescribing physician, of which there is no allegation or evidence here, plaintiff's pharmacy was required to dispense plaintiff a generic form of Topiramate, citing ****4** Education Law § 6810(6)(a);[4] Public Health Law § 206(1)(o).[5]

***3** In opposition, plaintiff argues that Janssen's motion should be denied without prejudice to renewal since, although it is "reasonably believed" that plaintiff received the Glenmark's generic version of Topamax, discovery is needed to confirm this fact. Moreover, plaintiff asserts that while it has been diligent in attempting to obtain plaintiff's medical and pharmacy records, such records are not conclusive. However, the court notes that the records submitted by plaintiff show that plaintiff was prescribed Topiramate, and not Topamax.

****5** "A CPLR 3211(a)(7) motion ...may be used to dispose of an action in which the plaintiff identifie[s] a cognizable cause of action but fail[s] to assert a material allegation necessary to support the cause of action." *Basis Yield Alpha Fund v. Goldman Sachs. Group, Inc.*, 115 AD3d 128, 134 (1st Dept 2014). In support of such a motion, "a defendant can submit evidence in support of the motion attacking a well-pleaded cognizable claim... [and] if the defendant's evidence establishes that the plaintiff has no cause of action (i.e., that a well-pleaded cognizable claim is flatly rejected by the documentary evidence), dismissal would be appropriate." Id at 135 (internal citations omitted).

The courts have held that named-brand drug manufacturers, like Janssen, cannot be held liable to the user of the generic form of their drug, since the manufacturer of the brand named drug owes no duty to the user of the drug's generic form. *See Weese v. Pfizer*, 2013 WL 5691993, *2 (Sup Ct NY Co. 2013)(dismissing product liability claims against Pfizer, the named brand manufacturer of the drug Zoloft, when the injuries were allegedly caused by ingestion of the Zoloft's generic form, noting that Pfizer's "duty should not extend to products and labeling over which it has no control, even if those products and labels mirror its own, because it has done nothing toward putting them in the hands of consumers"); *Coleson v. Janssen Pharmaceutical, Inc.*, 251 F. Supp3d 716 (SD NY 2017)("[T]he New York authorities are consistent with the majority of other courts around the country in rejecting liability for a company that itself did not manufacture, sell, or distribute generic versions of its name-brand drug."); *Goldych v. Eli Lilly & Co.*, 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006) (holding that name-brand manufacturer had "no duty to the users of other manufacturers' products").

Here, assuming *arguendo* that the complaint adequately asserts claims against Janssen, ****6** based on allegations that plaintiff was injured in connection with the use of its product, Topamax, the documentary and other evidence flatly contradicts these allegations. Specifically, the pharmacy records submitted by plaintiff show that plaintiff was prescribed Topiramate from April 16, 2014 through March 22, 2017. In addition, as noted by Janssen, New York law requires that, absent an explicit instruction from the prescribing physician, which plaintiff has not alleged or argued is the case here, plaintiff's pharmacy was required to dispense plaintiff a generic form of Topiramate. *See* Education Law § 6810(6)(a); Public Health Law § 206(1)(o).

Accordingly, as the documentary evidence establishes that plaintiff did not use Janssen's Topamax, and as Janssen cannot be held liable for any injuries sustained by plaintiff based on her use of Topiramate, the action must be dismissed as against Janssen.

Glenmark's Motion

Glenmark moves to dismiss the claims against it arguing that they are based on New York tort law regarding failure to warn and design defects and are thus preempted by federal law regarding requirements for generic drug manufacturers, citing *PLIVA, Inc. v. Mensing*, 564 US 604 (2011)(holding that federal law requiring generic drug manufacturers to use the same label as the brand named drug pre-empted state laws imposing duty to change a drug's label upon generic drug manufacturers); *Mutual Pharmaceutical Co., Inc. v Bartlett*, 570 US 472 (2013)(holding that federal law requiring generic drug manufacturers to be chemically equivalent to the approved brand-name drug preempted states law regarding design defects). Alternatively, Glenmark moves to dismiss the claims against it on the grounds that they are not adequately pleaded.

***4** In opposition, plaintiff does not dispute that her failure to warn claims would be preempted to the extent that Glenmark's generic Topiramate label are the same as the Janssen's ****7** label for the brand-name Topamax. Nor does plaintiff deny that any claims for design defects would be preempted by federal law requiring that Topiramate be chemically equivalent to Topamax under the holding in *Barlett supra*.

Plaintiff, however, argues that preemption does not apply to her allegations of failure to warn as the warning label for Glenmark's generic Topiramate, is not the same as name brand Topamax, citing *In re Fosamax Products Liability Ligation*, 965 FSupp2d 413 (SD NY 2013)(holding that the claims that manufacturers of generic drug allegedly failed to update labels to match the name brand drug are not preempted by federal law). In support of her opposition, plaintiff submits a patient insert for Janssen's Topamax, as revised in December 2014 (Plaintiff's Opp, Exh F), and a patient insert and product label for Glenmark's generic Topiramate as revised in July 2017 (Id, Exhs. H, I), which contain different warnings with respect to the effect of the use of the drug on the user's vision. In particular, plaintiff notes that Topiramate label and insert do not include the phrases in the Topamax insert regarding "untreated elevated intraocular pressure" and "these have been reported independent of elevated intraocular pressure." Plaintiff argues therefore that the Topiramate label is "confusing, ambiguous and significantly different from the FDA approved Janssen warnings."

In reply, Glenmark asserts that plaintiff's argument that preemption does not apply to the failure to warn claims as the warning label on Topiramate is not identical to that of Topamax is without merit since the labels and inserts relied on by plaintiff are from different time frames, that is Glenmark's Topiramate label and insert is the version based on a revision in July 2017, while Janssen's Topamax label is the version revised in December 2014. Moreover, Glenmark argues that the record shows that during the time period between December 2014 and July 2017, ****8** both Janssen and Glenmark updated their labels. In support of its position, Glenmark submits the label for Glenmark's generic Topiramate, as revised in December 2014, and Janssen's Topamax label as revised in December 2014, and notes that the relevant warning language with respect to possible effects of the drug on the user's vision is the same in each of the labels. [6] Glenmark also ****9** points out that the complaint alleges that plaintiff used Topiramate during the period when the December 2014 label would have been in effect. [7]

***5** The Supremacy Clause of the United States Constitution establishes that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2." *Mensing*, 564 US at 617. Thus, "where state and federal law directly conflict, state law must give way [and]. [s]uch a conflict exists where it is impossible for a private party to comply with both state and federal requirements." *Id.* (internal citations and quotations omitted); *see also*, *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)(noting that the "impossibility" preemption, occurs when it is "impossible for a private party to comply with both state and federal requirements").

In *Mensing*, United States Supreme Court held that state law failure-to-warn claims were preempted by federal law requiring that a generic drug's labeling must be the same as the brand name drug, which is the basis for the generic drug's approval. [8] Specifically, the Court held that ****10** "impossibility preemption" applied since it would be impossible for generic drug manufacturers "to comply with both with their state-law duty to change the label and their federal law duty to keep the label the same." *Mensing*, 564 US at 618.

Under the holding in *Mensing*, to the extent that Glenmark's generic Topiramate has the same labeling as Janssen's name-brand drug, Topamax, the label would be in compliance with federal law and preempt any state law claims based on allegations of failure to warn. Here, the record establishes that the relevant warning on the Topiramate label as revised in December 2014 is the same as that on the Topamax label as revised in December 2014. In reaching this conclusion, the court notes the labels for Topiramate and Topamax submitted by plaintiff in opposition are from different time periods. As Glenmark has shown that its Topiramate label, as revised in December 2014, was the same as the Topamax label for the same time period, the Topiramate label is in compliance with the sameness requirement under federal law, and plaintiffs failure to warn claims relating to her use of Topiramate beginning in December 2014 are preempted by federal law. [9]

***6 **11** Based on this holding, plaintiff's claims for strict liability, negligence, breach of express warranty and violations of the GBL, which are grounded in part on an alleged failure to warn, are preempted to the extent such claims relate to plaintiff's use of Topiramate beginning in December 2014. However, as discussed below, based on the record before the court, which does not include any evidence as to labeling of Topiramate (or Topamax) before December 2014, it cannot be established that the failure to warn claims based on plaintiff's alleged Topiramate use during the earlier period, that is from April 2014 to December 2014, are preempted by federal law.

With regard to design defect claims, such claims relate to the chemical composition of Topiramate. As it is undisputed that generic Topiramate is chemically equivalent to the approved brand name drug Topamax, to the extent plaintiff's claims for strict liability, negligence, breach of implied warranty, are grounded in allegations of design defects, they are preempted by federal law. *See Bartlett*, 570 US at 487. Moreover, unlike the failure to warn claim, the finding of preemption applies throughout the period of plaintiff's alleged use of Topiramate.

The court now turns to the remaining issue, which is whether during the period for which the record does not establish preemption applies, that is from April 2014 to December 2014, the ****12** the claims against Glenmark grounded in a failure to warn are sufficient to state a cause of action.

On a motion to dismiss for failure to state a cause of action under CPLR 3211(a)(7), the court "accept[s] the facts as alleged in the complaint as true, accord plaintiff[ ] the benefit of every possible favorable inference, and determine only whether the facts as alleged fit within any cognizable legal theory." *Leon v. Martinez*, 84 NY2d 83, 87-88 (1994). "Dismissal of the complaint is warranted [however] if the plaintiff fails to assert facts in support of an element of the claim, or if the factual allegations and inferences to be drawn from them do not allow for an enforceable right of recovery." *Connaughton v. Chiptole Mexican Grill, Inc.*, 29 NY3d 137, 142 (2017). [10]

As for the claims of strict liability and negligence based on the failure to warn, "negligence and strict liability claims [are viewed] as equivalent." *Estrada v. Berkel Inc.*, 14 AD3d 529, 530 (2d Dept 2005) (internal citation omitted). To state a claim for failure to warn, a plaintiff must prove that "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 Fed.Appx. 8, 10 (2d Cir.2011), citing *Liriano v. Hobart Corp.*, 92 NY2d 232, 237 (1998)

It has been held that "a failure to warn cause of action is appropriately dismissed if a ****13** plaintiff does not plead facts indicating how the provided warnings were inadequate." *Reid v. Pfizer, Inc.*, 839 FSupp2d 571, 575 (ED NY 2012). Here, the complaint alleges that the Topiramate warning is defective "because of the lack of adequate warnings regarding the propensity to cause [the] loss of vision as caused in plaintiff...by Topiramate [and that] the warnings violate both federal and state law" (Complaint ¶'s 24, 25). The court finds that under liberal pleading requirements, such allegations are sufficient at this juncture to state a claim for a defective warning. *See Nagel v. Brothers Intern. Food, Inc.*, 34 AD3d 545, 548 (2d Dept 2006)(noting that "in all but the most unusual circumstances, the adequacy of a warning is a question of fact"); *but see*, *Goldin v. Smith & Nephew, Inc.*, 2013 WL 1759575, *5 (SD NY 2013)(granting motion to dismiss failure to warn claim where plaintiff failed to "identify the allegedly defective warnings, nor does she allege facts in support of her claim that these warnings were,

in fact, defective"). Accordingly, the complaint states a claim for strict liability and negligence based on the failure to warn to the extent such claims have not been shown to be preempted by federal law during plaintiffs alleged use of Topiramate between April 2014 and before December 2014.

***7** As for the claim for breach of express warranty, such claim alleges, *inter alia*, that Glenmark expressly warranted that Topiramate "was safe and effective for those patients requiring psychiatric treatment and would not cause uveitis and plaintiff's other eye problems that develop directly from its use...[and that]... Topiramate...[as]...labeled, sold and distributed did not conform with those express representations...[and that] as a proximate result of [such] breach of warranty plaintiff has suffered serious injury." (Complaint ¶'s 36, 37). To state a claim for breach of express warranty, it must be shown that there was an "affirmation of fact or promise ****14** by the seller, the natural tendency of which [was] to induce the buyer to purchase, and that the warranty was relied upon." *Schimmenti v. Ply Gem Indus., Inc.*, 156 AD2d 658, 659 (2d Dept 1989). Here, absent from the complaint is any allegation that plaintiff or her doctor relied on the alleged express warranties prior to plaintiff using Topiramate, or that such reliance induced their purchase of drug. Accordingly, the claim for breach of express warranties is insufficient to state a claim.

The next claim alleges violations of GBL §§ 349 and 350 based on allegations that Glenmark engaged in "unfair competition or unfair or deceptive acts or practices when [it] failed to disclose to the FDA, to plaintiff and/or plaintiff's physician known dangers of... Topiramate causing certain eye sensitivities and uveitis" (Complaint ¶ 44). It is further alleges that the conduct included "false and misleading representations and omissions of material facts regarding safety and potential risks of ...Topiramate [and]...concealment, suppression or omission of material facts in connection with the sale of merchandise" and that "[t]he FDA, plaintiff and/or plaintiff's physicians relied upon [Glenmark's] misrepresentations and omissions" (Id ¶'s 47, 48), and plaintiff was harmed as a proximate cause of the alleged conduct.

To state a claim under GBL § 349, a plaintiff must allege that the defendant engaged "in an act or practice that is deceptive or misleading in a material way and that plaintiff has been injured by reason thereof." *Small v. Lorillard Tobacco Co.*, 94 NY2d 43, 55 (1999)(internal citations and quotations omitted). Deceptive or misleading representations or omissions are defined as those "likely to mislead a reasonable consumer acting reasonably under the [plaintiff's] circumstances." *Solomon v. Bell Atlantic Corp.*, 9 AD3d 49, 52 (1st Dept 2004)(internal citations and quotations omitted). The deceptive act or practice must be "the ****15** actual misrepresentation or omission to a consumer," *Goshen v. Mutual Life Ins. Co. of New York*, 98 NY2d 314, 325 (2002), by which the consumer is "caused actual, although not necessarily pecuniary, harm." *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 NY2d 20, 26 (1995). To qualify for protection under the statute, it must be shown that "the acts or practices have a broader impact on consumers at large [and] [p]rivate contract disputes, unique to the parties, ... would not fall within the ambit of the statute." Id at 25.

Here, plaintiff has adequately alleged a material deceptive act in the form of the failure to disclose the known dangers of Topiramate. Moreover, as Topiramate was made available to the public at large, there is no dispute that the alleged acts are "consumer oriented" for the purpose of the statute. Accordingly, to the extent that the claim for failure to warn has not been shown to be preempted, that is for the period between April 24, 2014 and before December 2014, the complaint states a claim for violation of GBL § 349.

As for GBL § 350, to state a claim under this section, which proscribes "[f]alse advertising in the conduct of any business, trade or commerce," a plaintiff must allege that the advertisement "(1) had an impact on consumers at large, (2) was deceptive or misleading in a material way, and (3) resulted in injury." *Andre Strishak & Assocs., P.C. v. Hewlett Packard Co.*, 300 AD2d 608, 609 (2d Dept 2002). Moreover, a plaintiff must show that she relied "upon or [was] aware of the allegedly false advertisement when purchasing the [product]." Id at 610. Here, as the complaint contains no allegations that plaintiff (or her physician) relied on any false advertisement of Topiramate before purchasing the drug, thee GBL § 350 claim fails to state a cause of action.

****16** ***Conclusion***

***8** In view of the above, it is

ORDERED that the motion by defendants Glenmark Pharmaceuticals, Inc., Glenmark Pharmaceuticals Inc., USA, and Glenmark Generics (motion sequence 002) is granted to the extent of dismissing the claims against them as preempted by federal law except insofar as the claims for strict liability, negligence, and violation of the General Business Law § 349 are based on a failure to warn for the period between April 24, 2014 and before December 2014; and it is further

ORDERED that the claims against defendants Glenmark Pharmaceuticals, Inc., Glenmark Pharmaceuticals Inc., USA, and Glenmark Generics for breach of implied breach of warranty is dismissed in its entirety as preempted by federal law; and it is further

ORDERED that plaintiffs claims for breach of express warranty and violation of General Business Law § 350 are dismissed for failure to state a cause of action; and it is further

ORDERED that within 20 days of efiling of this order, plaintiff shall efile an amended complaint consistent with this order; and it is further

ORDERED that defendants Glenmark Pharmaceuticals, Inc., Glenmark Pharmaceuticals Inc., USA, and Glenmark Generics shall answer the amended complaint within 30 days of the efiling of the amended complaint; and it is further

ORDERED that the motion to dismiss by defendants Janssen Pharmaceuticals, Inc., Janssen Ortho, LLC and Janssen Phrms (motion sequence 003) is granted; and it is further

ORDERED that the Clerk shall enter judgment dismissing the complaint as against defendants Janssen Pharmaceuticals, Inc., Janssen Ortho, LLC and Janssen Phrms; and it is ****17** further

ORDERED that the remaining parties shall appear for a preliminary conference on January 3, 2019, at 11:00 am, in Part 11, room 351, 60 Centre Street, New York, NY.

DATED: October 12, 2018

<<signature>>

J.S.C.

Footnotes

1 Motion sequence nos. 002 and 003 are consolidated for disposition.

2 Unless otherwise noted, the facts in the background section are based on the allegations in the verified complaint, which must be accepted as true for the purposes of this motion, plaintiff's affidavit, and Federal Drug Administration's public records available on its website, which are cited by the parties in their papers, and may be judicially noticed. *See Bertini. v. Smith & Nephew, Inc.*, 8 FSupp3d 246, 250 n. 1 (ED NY 2014) (taking judicial notice of FDA approval documents); *Gale v. Smith & Nephew, Inc.*, 989 FSupp. 2d 243, 246 n. 2 (SDNY 2013) (taking judicial notice of FDA public records available on FDA's website); *See also Kingsbrook Jewish Medical Center v. Allstate Ins Co.*, 61 AD3d 13, 20 (2d Dept 2009)(noting that judicial notice, as provided for under CPLR 4511(b) “has never been strictly limited to the constitutions, resolutions, ordinances, and regulations of government, but has been applied by case law to other

public documents that are generated in a manner which assures their reliability...including...material derived from official government websites...")(internal citation omitted).

3 While the complaint alleges that plaintiff was first prescribed Topamax and/or Topiramate on or about April 25, 2015, in plaintiff's affidavit which is submitted in connection with these motions, plaintiff states that her treatment began on or about April 16, 2014.

4 Section 6810(6)(a) of the New York State Education Law provides, in part, that:

a) Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing one line for the prescriber's signature. The prescriber's signature shall validate the prescription. Every electronic prescription shall provide for the prescriber's electronic signature, which shall validate the electronic prescription Imprinted conspicuously on every prescription written in this state in eight point upper case type immediately below the signature line shall be the words: "THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW". Unless the prescriber writes d a w in such box in the prescriber's own handwriting or, in the case of electronic prescriptions, inserts an electronic direction to dispense the drug as written, the prescriber's signature or electronic signature shall designate approval of substitution by a pharmacist of a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law. No other letters or marks in such box shall prohibit substitution. No prescription forms used or intended to be used by a person authorized to issue a prescription shall have 'd a w' preprinted in such box. Such box shall be placed directly under the signature line and shall be three-quarters inch in length and one-half inch in height, or in comparable form for an electronic prescription as may be specified by regulation of the commissioner. Immediately below such box shall be imprinted in six point type the words "Dispense As Written."

5 Public Health Law § 206(1)(o) mandates that the commissioner of the Department of Health "establish and publish a list of drug products" which are FDA approved and medically equivalent generic drug products.

6 The Topamax and Topiramate December 2014 labels contain the following language within the "highlights" section:

• Acute myopia and secondary angle closure glaucoma: Untreated elevated intraocular pressure can lead to permanent visual loss. The primary treatment to reverse symptoms is discontinuation of [Topamax or Topiramate] as rapidly as possible (5.1)

• Visual field defects: These have been reported independent of elevated intraocular pressure. Consider discontinuation of [Topamax or Topiramate](5.2)

The label also provides that:

5.1 Acute Myopia and Secondary Angle Closure Glaucoma

A syndrome consisting of acute myopia associated with secondary angle closure glaucoma has been reported in patients receiving [Topamax or Topiramate]. Symptoms include acute onset of decreased visual acuity and/or ocular pain. Ophthalmologic findings can include myopia, anterior chamber shallowing, ocular hyperemia (redness), and increased intraocular pressure. Mydriasis may or may not be present. This syndrome may be associated with supraciliary effusion resulting in anterior displacement of the lens and iris, with secondary angle closure glaucoma. Symptoms typically occur within 1 month of initiating [Topamax or Topiramate] therapy. In contrast to primary narrow angle glaucoma, which is rare under 40 years of age, secondary angle closure glaucoma associated with topiramate has been reported in pediatric patients as well as adults. The primary treatment to reverse symptoms is discontinuation of [Topamax or Topiramate] as rapidly as possible, according to the judgment of the treating physician. Other measures, in conjunction with discontinuation of [Topamax or Topiramate], may be helpful. Elevated intraocular pressure of any. etiology, if left untreated, can lead to serious sequelae including permanent vision loss.

5.2 Visual Field Defects

Visual field defects (independent of elevated intraocular pressure) have been reported in clinical trials and in postmarketing experience in patients receiving topiramate. In clinical trials, most of these events were reversible after topiramate discontinuation. If visual problems occur at any time during topiramate treatment, consideration should be given to discontinuing the drug.

7 Glenmark also submits a Topiramate label that was revised in February 2015 (Glenmark's motion, Exh. 2). To the extent plaintiff's counsel asserted at oral argument that the February 2015 label is evidence that Glenmark failed to timely update Topiramate label to match the Topamax label revised in December 2014, such argument is belied by the fact that

the record contains a Topiramate label revised in December 2014 which, as noted above, has the same relevant warning language as the December 2014 Topamax label.

8 Under federal law, a generic drug manufacturer may obtain approval of a drug from the FDA simply by showing equivalence to a reference-listed drug that has already undergone clinical trials and gained approval from the FDA. 21 U.S.C. § 355(j)(2)(A). A generic drug manufacturer has the responsibility to ensure that the labeling for the generic drug is the same as the labeling approved for the listed drug. 21 U.S.C. § 355(j)(2)(A)(v) & (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8) & 314.127(a)(7). The FDA interprets these regulations as imposing an ongoing duty for generic manufacturers to update their product labels to ensure the sameness of the generic and name-brand drug labels. *See Mensing*, 564 US at 612-613; 57 Fed.Reg. 17961 (1992) ("Abbreviated New Drug Application (ANDA) product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval").

9 The documents submitted by Glenmark in reply indicate that while Janssen revised its Topamax label in May 2017 (Glenmark's reply, Exh. 4), Glenmark did not revise its label to match Janssen's updated label until July 2017 (Id, Exh. 3). Even assuming *arguendo* this delay in updating the label would provide a basis for failure update claim, which type of claim is not preempted by federal law (*In re Fosamax Products Liability Litigation*, 906 FSupp2d at 417), here the complaint does not contain any allegations to make out such a claim, nor does plaintiff argue in opposition to the motion that she should be permitted to assert such a claim based on Glenmark's failure to timely update its label in 2017. In addition, plaintiff does not allege in her complaint or state in her affidavit, that she used, or obtained a prescription for, Topiramate during the time that she would have been affected by any failure by Glenmark to update its label in May 2017. In this connection, as noted herein, the pharmaceutical records show that plaintiff's last prescription for Topiramate was obtained in March 2017. Moreover, while the record contains a letter from plaintiff's counsel dated March 28, 2018, submitted in response to the court's inquiry at oral argument on motion sequence no. 004, which advised the court that plaintiff stopped taking the medication in June 2017, such unsupported statement is insufficient to provide a basis for finding a claim for failure to update the label, where the complaint alleges no such claim and the evidence shows that plaintiff's last prescription was filled in March 2017.

10 "In a products liability action, identification of the exact defendant whose product injured the plaintiff is...generally required." *Hymowitz v. Eli Lilly & Co.*, 73 NY2d 487, 504 (1989). Here, while plaintiff does not specify whether Janssen's product or Glenmark's product injured the plaintiff, as it has been found that the plaintiff used Glenmark's product, this pleading defect is not dispositive here.

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2012 WL 4757253 (Pa.Com.Pl.) (Trial Order)
Court of Common Pleas of Pennsylvania,
First Judicial District.
Philadelphia County

Stephen M. MADDEN, Appellant,
v.
TEVA PHARMACEUTICALS USA, INC. and Teva Pharmaceuticals Industries, Ltd. and Sanofi-Aventis US LLC and Sanofi-Aventis, Appellees.

No. 0087.
October 1, 2012.

Opinion

Allan L. Tereshok, Judge.

TRIAL DIVISION - CIVIL

OCTOBER TERM, 2010

Superior Court No. 1936 EDA 2012

Tereshko, J.

PROCEDURAL HISTORY

Plaintiff Stephen M. Madden appeals this Court's Order dated January 3, 2011, sustaining Defendant Sanofi-Aventis U.S., LLC's Preliminary Objections and dismissing any and all claims against Sanofi-Aventis U.S., LLC, with prejudice.

FACTUAL BACKGROUND

On September 20, 2008, Stephen M. Madden (hereinafter "Plaintiff") was prescribed Ambien 10 mg by a physician in Everett, Washington, following a total right knee replacement surgery. (Compl. ¶ 30). Ambien, and its generic bioequivalent, Zolpidem tartrate (hereinafter "Zolpidem"), is a sedative-hypnotic drug indicated for the short-term treatment of insomnia and intended to induce sleep. (Compl. ¶ 29). Plaintiff filled the prescription on October 1, 2008 at a Walgreens pharmacy in Redding, California. (Compl. ¶ 31). The pharmacist filled the prescription with the generic version of Ambien, Zolpidem 10 mg, manufactured by Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. Plaintiff ingested Zolpidem as directed, before bedtime on October 2, 2008. (Compl. ¶ 33).

At or around midnight on October 3, 2008, Plaintiff got into his car and drove his vehicle off of the road and into a ditch. (Compl. ¶ 34). Plaintiff continued to drive the vehicle, colliding with fences and fence posts on Old Oregon Trail in Redding, California. (Compl. ¶ 34). Plaintiff ultimately crashed his vehicle at a high rate of speed into a tree and electric pole, causing him to be ejected from the vehicle to a distance between thirty (30) and fifty (50) feet. (Compl. ¶ 34).

In the early morning of October 3, 2008, Plaintiff was transported in critical condition by ambulance to the Trauma Room of Mercy Medical Center Redding in Redding, California. (Compl. ¶ 36). As a direct result of the single vehicle accident, Plaintiff suffered head and multiple system trauma, lacerations and swollen soft tissues, multiple severe facial fractures, a skull fracture with traumatic head injury, brain swelling, multiple rib fractures with pulmonary contusion, hypoxia, and multiple fractures to the lumbar spine, radius and ulna. (Compl. ¶ 38). Plaintiff's blood tested negative for intoxicants. (Compl. ¶ 37).

Plaintiff remained in the hospital for treatment until he was discharged to a rehabilitation center in December 2008. (Compl. ¶ 39). Plaintiff continues to reside in a convalescent home in Sylmar, California. (Compl. ¶ 40). Plaintiff has no recollection of driving and crashing his vehicle. (Compl. ¶ 40).

Sleep-driving is a term that refers to driving while not fully awake, after ingestion of a sedative-hypnotic, with amnesia for the event. (Compl. ¶ 41). Plaintiff states in his complaint that sleep-driving is a dangerous and known risk associated with Ambien and its generic bioequivalent, Zolpidem. (Compl. ¶ 41). Sleep-driving may manifest as early as the first dose or after periods of uneventful use. (Compl. ¶ 42).

Plaintiff commenced this action on October 4, 2010 by filing a Complaint in the Court of Common Pleas of Philadelphia County against four defendants: Teva Pharmaceuticals USA, Inc. (hereinafter "Teva"), Teva Pharmaceuticals Industries, Ltd. [1], Sanofi-Aventis U.S., LLC [2] (hereinafter "Sanofi") and Sanofi-Aventis. [3] *See Docket.* On November 15, 2010, Sanofi filed Preliminary Objections to Plaintiff's Complaint. *Id.* On December 6, 2010, Plaintiff filed an Answer in Opposition to Sanofi's Preliminary Objections. *Id.* On December 13, 2010, Sanofi filed a Reply in Support of Preliminary Objections. By Order dated January 4, 2011, Judge Tereshko sustained Sanofi's Preliminary Objections and dismissed any and all claims against Sanofi, with prejudice. *Id.*

Teva filed Preliminary Objections to Plaintiff's Complaint on February 15, 2011. *Id.* By Order dated May 3, 2011, the Honorable Judge Lisa M. Rau overruled Teva's Preliminary Objections and directed Teva to file an Answer to Plaintiff's Complaint within twenty (20) days of the Order. *Id.* Teva filed an Answer with New Matter to Plaintiff's Complaint on July 6, 2011. *Id.* On July 26, 2011, Plaintiff filed a Reply to Teva's New Matter. *Id.* On April 23, 2012, Teva filed a Motion for Judgment on the Pleadings and on May 7, 2012, Teva filed a Motion for Extraordinary Relief. *Id.*

By Order dated May 10, 2012, the Honorable Nitza I. Quinones-Alejandro granted Teva's Motion for Extraordinary Relief, extending the case management deadlines by sixty (60) days. *Id.* Judge Quinones-Alejandro granted Teva's Motion for Judgment on the Pleadings by Order dated May 21, 2012, dismissing Teva, with prejudice. *Id.*

On June 20, 2012, Plaintiff timely appealed the Court's Order dated January 3, 2011. *Id.* On July 23, 2012, Plaintiff filed his Rule 1925(b) Statement of Matters Complained of pursuant to this Court's Order dated July 2, 2012.

The issues on appeal are:

> 1. Whether the Court erred in concluding that Washington law applies to the present litigation after analyzing the case utilizing Pennsylvania conflict of law principles; and
>
> 2. Whether the Court erred in granting Sanofi's Preliminary Objections and dismissing Plaintiff's Complaint with prejudice, declining to hold Sanofi responsible for the labeling of the generic version of the drug Ambien pursuant to *Wyeth v. Levine,* 129 S. Ct. 1187 (2009), and *Pliva, Inc. v. Mensing,* 131 S. Ct. 2567 (2011).

LEGAL ANALYSIS

Pennsylvania Rule of Civil Procedure 1028(a)(4) permits a party to file a preliminary objections in the form of a demurrer to any pleading lacking legal sufficiency. Pa.R.C.P 1028(a)(4). The issue raised by a demurrer is whether the facts in the pleading itself are sufficient to entitle a claimant to relief. *Int'l Union of Operating Eng'rs, Local No 66, AFL-CIO v. Linesville Const. Co.,* 457 Pa. 220, 223, 322 A.2d 353, 356 (1974). A preliminary objection in the nature of a demurrer will be sustained only where the pleading, on its face, is insufficient to establish the pleader's right to relief. *Willet v. Pa. Med. Catastrophe Loss Fund,* 549 Pa. 613, 619, 702 A.2d 850, 853 (1997). In determining whether to sustain the demurrer, the court must admit as true all well-pleaded, material, relevant facts set forth in the pleading and all reasonable inferences that may be drawn therefrom. *Id.*

Plaintiff avers that this Court erred in applying Washington law to the present litigation. Plaintiff filed his Complaint in Pennsylvania, but makes several claims against Sanofi based on events that occurred outside the Commonwealth. This raises a threshold conflict-of-law question that must be addressed to determine the substantive law that applies to Plaintiff's claims. In determining the applicable substantive law, for cases filed within the Commonwealth, Pennsylvania courts apply Pennsylvania conflict-of-law principles. *Klaxon Co. v. Stentor Elec. Mfg. Co.,* 313 U.S. 487, 61 S.Ct. 1020, 85 L.Ed 1477 (1941).

Pennsylvania has abandoned the traditional "place of injury" approach to conflicts of law in favor of a more flexible approach. *Griffith v. United Air Lines, Inc.,* 416 Pa. 1, 23, 203 A.2d 796, 806 (1964). Under Pennsylvania law, conflicts of law are analyzed using a hybrid approach that "combines the approaches of both Restatement II (contacts establishing significant relationships) and 'interest analysis' (qualitative appraisal of the relevant States' policies with respect to the controversy)." *Melville v. Am. Home Assurance Co.,* 584 F.2d 1306, 1311 (3d Cir. 1978). In this case, both the significant relationship and interest analysis favor applying Washington law to Plaintiff's claims against Sanofi.

Section 145 of the Restatement II provides as follows:

> (1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.
>
> (2) Contacts to be taken into account in applying the principles of § 6 to determine the law applicable to an issue include:

(a) the place where the injury occurred,

(b) the place where the conduct causing the injury occurred,

(c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and

(d) the place where the relationship, if any, between the parties is centered.

> These contacts are to be evaluated according to their relative importance with respect to the particular issue. Restatement (Second) of Conflict of Laws § 145 (1971).

Plaintiff contends that this Court erred in applying Washington law to the present litigation when both the site of the accident and the residence of the plaintiff lay in California. None of Plaintiff's contacts with California, however, are pertinent to Plaintiff's claims against Sanofi. An analysis of the contacts relevant to Plaintiff's claims against Sanofi demonstrates that the relevant (and only) contact occurred in Washington.

Plaintiff seeks recovery against Sanofi based on two theories of liability: negligence and negligent misrepresentation. See Compl. P. 34-50. The facts alleged by Plaintiff indicate that the entire connection between Plaintiff and Sanofi, if any, begins and ends in Washington, and any conduct on the part of Sanofi that allegedly caused injury to Plaintiff would have therefore

occurred in Washington. According to Plaintiff's Complaint, "On or about September 20, 2008, Plaintiff was prescribed the drug Ambien ... by a physician in Everett, State of Washington..." (Compl. ¶ 30). Any and all relevant contact with Sanofi ends at this point in Everett, Washington. Plaintiff filled the prescription on October 1, 2008 in California with the generic drug Zolpidem, manufactured by Teva. (Compl. ¶¶ 31-32). All of the remaining events, including Plaintiff's alleged ingestion of Zolpidem and subsequent accident, occurred after he purchased the medication manufactured by Teva.

An "interest analysis" indicates that Washington also has the greater interest in having its law applied to the claims against Sanofi. At the center of Plaintiff's claims against Sanofi are allegations regarding the prescription written by a Washington physician and the information relied upon by that Washington physician. Washington recognizes the learned intermediary doctrine, which provides that the manufacturer or supplier of prescription drug has no legal duty to warn a consumer of the dangerous propensities of its drug, as long as adequate warnings are provided to the prescribing physician. *Estate of LaMontagne v. Bristol-Myers Squibb,* 127 Wash.App. 335, 345, 111 P.3d 857, 862 (2005).

Based on Plaintiff's allegations, the decision to prescribe Ambien was made in Washington, the prescription was written in Washington, and any warnings to the doctor would necessarily have been received in Washington. Therefore, any claims of negligence or negligent misrepresentation would be based on a representation to the prescribing physician in Washington; the physician's reliance on that misrepresentation would also have occurred in Washington. Accordingly, Washington has an interest in having its law applied to determine whether or not such allegations amount to a cognizable claim. Washington also has a general interest in ensuring that its law is applied to products liability claims involving alleged representations within its borders.

Moreover, Washington has a significant interest in ensuring that its physicians receive adequate information regarding the risks of products that they prescribe, thus protecting physicians in the State of Washington from increased liability and insurance premiums that may ultimately be passed on to consumers in the form of increased healthcare expenses. This is consistent with the purpose of the Washington Product Liability Act (hereinafter "WPLA"), which was "designed to address a liability insurance crisis which could threaten the availability of socially beneficial products and services." *Wash. Water Power Co. v. Graybar Elec. Co.,* 112 Wash.2d 847, 850, 774 P.2d 1199, 1202 (1989); *see also* Wash. Rev. Code § 7.72.010, Preamble.

Permitting the significant expansion of liability that Plaintiff is seeking in this case would be in direct contrast to the goal of the WPLA and would only provide further disincentives to innovation and development as well as increased costs for consumers. Under Plaintiff's theory of liability, Sanofi would become a functional insurer for its competitor's products that it does not manufacture or sell. Ultimately, Washington has the greater interest in having its law applied to Plaintiff's claims against Sanofi.

Other states, including New Jersey, Pennsylvania, and California, have an interest in having their law applied as well. Sanofi's headquarters are located in New Jersey. Therefore, New Jersey arguably has an interest in regulating companies within its borders. Pennsylvania has an interest in applying its law in this case as the forum state. California has an interest in applying its law because Plaintiff resides in California, and the accident occurred in California. California's interest in having its law applied to Plaintiff's claims against Sanofi, however, is diluted for three reasons. First, Plaintiff traveled out of state to receive medical treatment. Second, Plaintiff's claims against Sanofi rely exclusively on alleged representations made by Sanofi to the prescribing physician in Washington. Finally, Plaintiff chose to file his lawsuit in Pennsylvania rather than California.

Considering the contacts and interests of the states involved, this Court properly concluded that Washington law should apply. The decision to prescribe Ambien was made in Washington, the prescription was written in Washington, and any warnings to Plaintiff's physician were given in Washington. On balance, these considerations favor application of Washington law.

Sanofi cannot be held liable for Plaintiff's injuries under the WPLA. The WPLA provides the exclusive remedy for product liability claims in Washington. *Graybar,* 112 Wash.2d at 853, 774 P.2d 1199. The WPLA subsumes virtually all prior causes of action, including negligence and negligent misrepresentation. [4] Consequently, Plaintiff's claims can only be brought, if they can be brought at all, under the WPLA.

Under the WPLA, product liability claims can only be brought against the manufacturer or seller of the "relevant product." *See* Wash. Rev. Code §§ 7.72.010(3)-(4); *See also Id.* at 7.72.030. The "relevant product" consists of the product or those component parts that actually caused the injury. *Sepulveda-Esquivel v. Cent. Mach. Works, Inc.,* 120 Wash.App. 12, 19-20 n.2, 83 P.3d 895, 899 n.2 (2004) ("We do not address the other defenses raised by the parties because the product must be the 'relevant product' before there can be liability. That issue is determinative.").

Sanofi was not the manufacturer or seller of the product at issue in this case. *See* §§ 7.72.010(1)-(2). Here, it is undisputed that the Plaintiff purchased and ingested the generic, Zolpidem, manufactured and sold by Teva, not the brand-name, Ambien, manufactured by Sanofi. Accordingly, Plaintiff cannot assert a legally sufficient claim against Sanofi under Washington law. As such, the Court properly dismissed Plaintiff's claims against Sanofi.

Finally, Plaintiff argues that federal law supports the notion that a pharmaceutical manufacturer can be liable for a product it did not manufacture or sell. Plaintiff cites *Wyeth v. Levine,* 129 S. Ct. 1187, 555 U.S. 555 (2009), and *PLIVA, Inc. v. Mensing,* 131 S. Ct. 2567 (2011), in support of this contention. *See* Appellant's Statement of Reasons for Appeal Under Rule 1925(b) ¶¶ 6-7. In *PLIVA,* the United States Supreme Court held that federal law pre-empted those state laws that imposed the duty to change a drug's label upon generic manufacturers. 131 S. Ct. at 2577-78.

In *Levine,* the Supreme Court of the United States held that FDA approval of a pharmaceutical product did not preempt state tort claims for failure to warn. 129 S. Ct. at 1204, 555 U.S. at 581. *Levine* held that "a central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its labeling at all times." *Id.* at 1198, 570-71. This premise is equally valid for a generic manufacturer as it is for a name-brand manufacturer. "Manufacturers of generic drugs, like all other manufacturers are responsible for the representations they make regarding their products." *Foster v. Am. Home Prods. Corp.,* 29 F.3d 165, 170 (4th Cir. 1994).

Here, the Court properly dismissed Plaintiff's claims against Sanofi because Sanofi was not the manufacturer or seller of the product ingested by the Plaintiff. Here, it is undisputed that the Plaintiff purchased and ingested the generic drug, Zolpidem manufactured and sold by Teva, not the brand-name drug, Ambien manufactured by Sanofi. Moreover, courts across the country have overwhelmingly refused to allow claims against the manufacturer of a name-brand medication for damages allegedly caused by the use of another manufacturer's generic-equivalent medication on both legal and policy grounds. [5]

In *Foster,* the Fourth Circuit addressed the precise theory Plaintiff asserts here:

> Using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control ... would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising.... 29 F.3d 165, 170-71 (4th Cir. 1994). Plaintiff has specifically alleged that Teva, not Sanofi, manufactured the product ingested by the Plaintiff. As such, Plaintiff has failed to state a legally sufficient claim against Sanofi.

CONCLUSION

For the foregoing reasons, this Court respectfully requests that its decision to sustain Sanofi-Aventis U.S., LLC's Preliminary Objections and dismiss any and all claims against Sanofi-Aventis U.S., LLC, with prejudice, be AFFIRMED.

BY THE COURT:

10/1/12

DATE

_____

ALLAN L. TERESHKO, J.

cc:

All counsel

Joseph P. Grimes, Esq., for Appellant

Alice Sacks Johnston, Esq., for Appellee Teva Pharmaceuticals

Kenneth Alonzo Murphy, Esq., for Appellee Sanofi-Aventis

Footnotes

1 Plaintiff attempted to serve Teva Pharmaceuticals Industries, Ltd. on October 14, 2010 but service was not accomplished. *See Docket.*

2 Sanofi-Aventis U.S., LLC is a pharmaceutical company that is incorporated in Delaware and headquartered in Bridgewater, New Jersey. (Compl. ¶ 5).Sanofi-Aventis U.S., LLC manufactures and sells the name-brand prescription medication Ambien in the United States - it does not sell or manufacture the generic form of zolpidem tartrate. (Compl. ¶ 18).

3 There is no such "Sanofi-Aventis" entity. (Def.'s Prelim. Objections to Pl.'s Compl. N. 1). To the extent that Plaintiff intended to name Sanofi-Aventis S.A., Sanofi-Aventis S.A. is a French corporation based in France. *Id.* Sanofi-Aventis S.A. does not manufacture or sell Ambien. *Id.* Moreover, Sanofi-Aventis S.A. has not been served in this matter and is not a proper party to this litigation. *Id.*

4 *See* Wash. Rev. Code § 7.72.010(4) (" 'Product liability claim' includes ... but is not limited to, any claim or action previously based on: Strict liability in tort; negligence; breach of express or implied warranty; breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment or nondisclosure, whether negligent or innocent ...").

5 To date, more than 40 cases in approximately 20 states have held that a name-brand manufacturer is not liable for injuries allegedly caused by the use of a generic manufacturer's product. *See, e.g., Foster v. Am. Home Prods. Corp.,* 29 F.3d 165, 171 (4th Cir. 1994); *Levine v. Wyeth, Inc.,* 684 F. Supp. 2d 1338, 1344 (M.D. Fla. 2010); *Fullington v. Pfizer, Inc.,* 2010 WL 3632747 (E.D. Ark. Sept 17, 2010); *Neal v. Teva Pharm. USA, Inc.,* 2010 WL 2640170, at *2 (W.D. Ark. July 1, 2010); *Mosley v. Wyeth Inc.,* 719 F.Supp.2d 1340 (S.D. Ala. 2010); *Craig v. Pfizer, Inc.,* 2010 WL 2649545, at *2-4 (Mag. E.D. La. May 26, 2010), *adopted,* 2010 WL 2649544 (W.D. La. June 29, 2010); *Finnicum v. Wyeth, Inc.,* 708 F.Supp.2d 616 (E.D. Tex. 2010); *Howe v. Wyeth Inc.,* 2010 WL 1708857, at *4-5 (M.D. Fla. Apr. 26, 2010); *Hardy v. Wieth, Inc.,* 2010 WL1049588, at *2-5 (Mag. E.D. Tex. March 8, 2010), *adopted,* 2010 WL 1222183 (E.D. Tex. Mar. 29, 2010); *Morris v. Wyeth, Inc.,* No. 09-0854, 2009 WL 4064103, at *4 (W.D. La. Nov. 23, 2009); *Meade v. Parsley,* No. 2:09-cv-00388, 2009 WL 3806716, at *3 (S.D.W. Va. Nov. 13, 2009); *Burke v. Wyeth, Inc.,* No. G-09-82, 2009 WL 3698480, at *2-3 (S.D. Tex. Oct. 29, 2009); *Stoddard v. Wyeth, Inc.,* 630 F.Supp.2d 631, 633-34 (E.D.N.C. 2009); *Fields v. Wyeth, Inc.,* 613 F. Supp. 2d 1056, 1061 (W.D. Ark. 2009); *Moretti v. Wyeth, Inc.,* No. 2:08-CV-00396, 2009

WL 749532, at *3-4 (D. Nev. Mar. 20, 2009); *Schrock v. Wyeth, Inc.,* 601 F. Supp. 2d 1262, 1266-67 (W.D. Okla. 2009); *Cousins v. Wyeth Pharm. Inc.,* No. 3:08-CV-0310-N, 2009 WL 648703, at *2 (N.D. Tex. Mar. 10, 2009); *Wilson v. Wyeth, Inc.,* No. 3:07-CV-378-R, 2008 WL 2677049, at *3-4 (W.D. Ky. June 30, 2008); *Smith v. Wyeth, Inc.,* No. 5:07-CV-18-R, 2008 WL 2677051, at *4 (W.D. Ky. June 30, 2008); *Morris v. Wyeth, Inc.,* No. 1:07-CV-176-R, 2008 WL 2677048, at *4 (W.D. Ky. June 30, 2008); *Pustejovsky v. Wyeth, Inc.,* No. 4:07-CV-103-Y, 2008 WL 1314902, at *2 (N.D. Tex. Apr. 3, 2008); *Swicegood v. Pliva, Inc.,* 543 F. Supp. 2d 1351, 1358 (N.D. Ga. 2008); *Barnhill v. Teva Pharms. USA, Inc.,* No. 06-0282-CB-M, 2007 WL 5787186, at *1-2 (S.D. Ala. Apr. 24, 2007); *LeBlanc v. Wyeth, Inc.,* No. Civ A 04-0611, 2006 WL 2883030, at *6 (W.D. La. Oct. 5, 2006); *Goldych v. Eli Lilly & Co.,* No. 5:04-CV-1477, 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006); *Colacicco v. Apotex, Inc.,* 432 F. Supp. 2d 514, 540-41 (E.D. Pa. 2006), *aff'd in pertinent part,* 521 F.3d 253 (3d Cir. 2008), *vacated and remanded on other grounds,* 129 S.Ct. 1578 (2009); *Possa v. Eli Lilly & Co.,* No. 05-1307, 2006 WL 6393160, at *1 (M.D. La. May 10, 2006); *Tarver v. Wyeth, Inc.,* No. Civ.A.3-04-2036, 2005 WL 4052382, at *2 (W.D. La. June 7, 2005); *Block v. Wyeth, Inc.,* No. CIV.A.3:02-1077, 2003 WL 203067, at *2 (N.D. Tex. Jan. 28, 2003); *DaCosta v. Novartis AG,* No. CV 01-800-BR, 2002 WL 31957424, at *8-9 (D. Or. Mar. 1, 2002); *Buchanan v. Wyeth Pharms. Inc.,* No. CV-2007-900065, 2008 WL 7136137 (Ala. Cir. Ct. May 15, 2007); *Sheeks v. Am. Home Prods. Corp.,* No. 02CV337, 2004 WL 4056060, at *2 (Colo. Dist. Ct. Oct. 15, 2004); *Dietrich v. Wyeth, Inc.,* No. 50-2009-CA-021586, 2009 WL 4924722, at *3-6 (Fla. Cir. Ct. Dec. 21, 2009); *Sharp v. Leichus,* No. 2004-CA-643, 2006 WL 515532, at *3 (Fla. Cir. Ct. Feb. 17, 2006), *aff'd per curiam,* 952 So. 2d 555 (Fla. Dist. Ct. App. 2007); *Reynolds v. Anton,* No. 01A-76719-3, 2004 WL 5000272, at *9 (Ga. Super. Ct. Oct. 28, 2004); *Huck v. Trimark Inc.,* 991 So. 2d 31, 34-35 (La. Ct. App. 2008); *Kelly v. Wyeth, Inc.,* No. CIV.A.MICV200303314B, 2005 WL 4056740, at *2 (Super. Ct. Mass. May 6, 2005); *Flynn. Am. Home Prods. Corp.,* 627 N.W.2d 342, 350 (Minn. Ct. App. 2001); *Westerlund v. Wyeth, Inc.,* No. MID-2174-05, 2008 WL 5592753, at *3 (N.J. Super. Ct. Oct. 20, 2008); *Sloan v. Wyeth, Inc.,* No. MRS-L-1183-04, 2004 WL 5767103, at *4 (N.J. Super. Ct. Oct. 13, 2004); *Beutella v. A.H. Robins Co.,* No. 980502372, 2001 WL 35669202, at *3 (Utah Dist. Ct. Dec. 10, 2001).

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Only the Westlaw citation is currently available.
United States District Court, D. Minnesota.

IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION
This Document Relates to:
David Butkiewicz v. Bayer Corp., Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma A.G., and Bayer, A.G.

MDL No. 2642 (JRT)
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Master Docket Case No. 0:15-md-02642
|
Case No. 0:19-cv-01602-JRT.
|
Signed 02/04/2021

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MEMORANDUM OPINION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS

JOHN R. TUNHEIM, Chief Judge

***1** Defendants, manufacturers of the brand-name drug Cipro, filed a Motion to Dismiss, asserting that each of Plaintiff David Butkiewicz's claims alleged only injuries related to his use of ciprofloxacin, the generic equivalent of Cipro, which Defendants did not manufacture, market, or distribute. Butkiewicz, a resident of Illinois, contends that he and his prescribing physician relied on the ciprofloxacin label created by Defendants, as required by federal law, which failed to adequately warn of the risk of peripheral neuropathy as a side effect of the drug. Therefore, Butkiewicz argues that Defendants breached their duty to him under Illinois common law, and that he was injured by their negligent and fraudulent labeling. Defendants disagree and urge the Court to reject Butkiewicz's theory of liability. Defendants posit that, although the Illinois Supreme Court has not addressed whether brand-name manufacturers may be liable for injuries caused by their warning labels when the label is affixed to a generic version of the drug, it would likely find that such claims are not viable.

Defendants are correct that Butkiewicz's strict liability and product liability – failure to warn claims fail as a matter of law because Defendants did not manufacture or distribute ciprofloxacin, and Butkiewicz's warranty claims fail because the parties were not in privity. Yet Butkiewicz may assert that Defendants are liable for his reliance-related injuries under theories of negligence, misrepresentation, and fraud with respect to their ciprofloxacin warning label. Under Illinois law, claims related to injuries caused by information about a product are distinct from product liability claims, and Defendants have a duty to all consumers who foreseeably rely on their warning label, irrespective of whether the consumer uses the brand name or generic form of the drug.

Accordingly, the Court will grant Defendants' Motion to Dismiss as it relates to Butkiewicz's strict liability, product liability – failure to warn, and breach of express and implied warranty claims, but will deny Defendants' Motion as it relates to Butkiewicz's remaining claims because they are cognizable and plausibly alleged.

BACKGROUND

I. FACTUAL BACKGROUND

Plaintiff David Butkiewicz was prescribed ciprofloxacin, a fluoroquinolone antibiotic, and used it as directed, (Compl. ("Individual Complaint") ¶¶ 30, 34, June 4 2019, Docket No. 1), from February to June 2013, (2nd Am. Compl. ("Amended MDL Short-Form Complaint") ¶¶ 8–9, Apr. 27, 2020, Docket No. 30).[1] Butkiewicz developed irreversible peripheral neuropathy. (Individual Compl. ¶ 3.) Due to misrepresentations by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG, and Bayer AG (collectively, "Defendants") in the ciprofloxacin warning label, Butkiewicz and his physicians did not recognize that he was suffering from permanent peripheral neuropathy caused by ciprofloxacin. (*Id.* ¶¶ 61–62.)

***2** Butkiewicz alleges that Defendants failed to appropriately and adequately inform consumers and their physicians of the serious and dangerous risks of irreversible peripheral neuropathy associated with the use of Cipro and ciprofloxacin. (2nd Am. Master Compl. ("MDL Master Complaint") ¶ 68, Aug. 12, 2016, MDL No. 15-2642, Docket No. 241). The ciprofloxacin label used from September 2004 to August 2013 indicated that only "rare" cases of peripheral neuropathy had been reported in patients receiving quinolones, and the label did not explicitly include ciprofloxacin as among the drugs posing a risk of peripheral neuropathy. (MDL Master Compl. ¶ 89.) Because of the inadequate label, patients received fluoroquinolones, such as ciprofloxacin, instead of acceptable and adequate non-fluoroquinolone antibiotics. (*Id.* ¶¶ 96–97.)

On August 15, 2013, an updated warning label and accompanying safety information was issued for ciprofloxacin, which included a warning about the risk of rapid onset, irreversible peripheral neuropathy. (*Id.* ¶ 90.)

However, Defendants knew peripheral neuropathy and related symptoms were among the most common side effects of fluoroquinolones, including ciprofloxacin, for more than a decade prior to the August 2013 label change. (*Id.* ¶¶ 120, 123, 139.) Despite this knowledge, Butkiewicz alleges, Defendants recklessly and intentionally misled patients and physicians from September 2004 through August 2013, (*id.* ¶¶ 152, 156), by aggressively marketing fluoroquinolones and concealing the risks through misrepresentations and omissions, (*id.* ¶¶ 126–27.)

Defendants, through paid medical consultants, allegedly "fraudulently and intentionally polluted the scientific literature related to the safety and efficacy" of ciprofloxacin. (*Id.* ¶ 231 (listing allegedly false statements about ciprofloxacin).) For example, a consultant named Peter Ball stated that, "Ciprofloxacin is well tolerated; the incidence of adverse events is low and serious adverse events are rare." (*Id.*) In 2001, Defendants, through Glenn Tillotson, a Bayer director and co-developer of Cipro, also allegedly sought to downplay the significance of the first major study finding peripheral neuropathy to be a permanent side effect of Cipro. (*Id.* ¶ 232.)

Butkiewicz asserts that Defendants intended consumers and physicians to rely on the misinformation in the ciprofloxacin warning label, (*id.* ¶ 164), and that he and his physician did so rely, (Individual Compl. ¶¶ 61–62.) Butkiewicz therefore alleges that his injuries were the direct and proximate result of Defendants' negligence, misrepresentations, and fraud in creating the ciprofloxacin warning label. (*See, e.g.*, MDL Master Compl. ¶¶ 212, 246, 254, 263.)

II. PROCEDURAL BACKGROUND

Butkiewicz filed a Complaint against Defendants in the Northern District of Illinois on June 4, 2019. (Individual Compl.) On June 18, 2019, Butkiewicz's case was transferred to the District of Minnesota for pretrial proceedings as part of Multidistrict

Litigation ("MDL") No. 2642. (Conditional Transfer Order, June 18, 2019, Docket No. 4.) Butkiewicz completed the individual MDL Short Form Complaint on April 13, 2020. (Am. Compl., Apr. 13, 2020, Docket No. 26.)

On April 27, 2020, Butkiewicz filed an Amended MDL Short Form Complaint, clarifying that he used generic ciprofloxacin. (Am. MDL Short Form Compl. ¶¶ 8–9.) Butkiewicz identified Illinois law as supporting his generics-related claims against the brand-name manufacturers.[2] (*Id.* ¶ 9.) Butkiewicz asserts claims for Strict Liability, Product Liability – Failure to Warn, Negligence, Breach of Express Warranty, Breach of Implied Warranty, Fraud, Negligent Misrepresentation, Fraudulent Concealment, and Violation of Consumer Protection/Consumer Fraud Law. (*Id.* ¶ 17.)

***3** On August 14, 2020, Defendants filed a Motion to Dismiss Butkiewicz's Amended MDL Short Form Complaint pursuant to Rule 12(b)(6), arguing Butkiewicz failed to state a claim against Defendants under Illinois law. (Mot. Dismiss, Aug. 14, 2020, Docket No. 34.)

DISCUSSION

I. STANDARD OF REVIEW

In reviewing a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court considers all facts alleged in the complaint as true to determine if the complaint states a "claim to relief that is plausible on its face." *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 594 (8th Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937. Although the Court accepts the complaint's factual allegations as true and construes the complaint in a light most favorable to the plaintiff, it is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986). In other words, a complaint "does not need detailed factual allegations," but it must include more "than labels and conclusions, and a formulaic recitation of a cause of action's elements" to meet the plausibility standard. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

II. ANALYSIS

A. Federal Duty of Sameness and Preemption

The obligations and limitations of brand-name and generic drug manufacturers are set by federal law. Most important here, the Hatch-Waxman Amendments streamlined the approval process for generic equivalents of brand-name drugs that had already been approved by the FDA. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612–13, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011) (citing 21 U.S.C. § 355). The simplified generics approval process requires the generic drug's design and warning label to be identical to the brand-name version at the time of approval. *Id.* at 613, 131 S.Ct. 2567.

In *Mensing*, the Supreme Court addressed whether generic manufacturers may change their labels after initial FDA approval. *Id.* The Supreme Court held that, unlike brand-name drugs, generic drug manufacturers cannot unilaterally change their warning labels after initial approval, since federal law requires that generic drug labels be the same as the corresponding brand-name drug label at all times. *Id.* at 618, 131 S.Ct. 2567. As such, state law tort claims against generic drug manufacturers asserting they have a duty to provide stronger warning labels are preempted by federal law. *Id.* However, state tort claims against brand-name manufacturers asserting they have a duty to provide stronger, adequate warnings are not preempted by federal law because federal regulations permit brand-name manufacturers to unilaterally revise drug warnings. *See Wyeth v. Levine*, 555 U.S. 555, 573, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009).

B. Brand-Name Manufacturer Warning Label Liability

As a result of the federal "duty of sameness," which requires generic drug manufacturers to use warning labels created by brand-name manufacturers, *see Mensing*, 564 U.S. at 618–19, 131 S.Ct. 2567, consumers have sought to hold brand-name manufacturers liable under state tort law for injuries caused by defects in generic drug labels. Many courts, however, have been unreceptive to these claims, concluding that brand-name manufacturers should not be held liable for injuries caused by drugs they did not produce, irrespective of how the claim is styled, whether as a products liability claim or a negligence or misrepresentation claim. *See Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013) ("[T]he overwhelming national consensus—including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product."). Courts also frequently cite policy concerns about the potential effects that permitting such claims might have on the pharmaceutical industry overall. *See, e.g.*, *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014) ("[T]here are grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher priced brand name drugs and fewer innovative drugs.").

***4** Many cases rejecting brand-name manufacturers' liability for warning labels on generic products rely, in part, on the Fourth Circuit's decision in *Foster v. American Home Products Corp*, which held that "a name brand manufacturer cannot be held liable on a negligent misrepresentation theory for injuries resulting from use of another manufacturer's product[.]"[3] 29 F.3d 165, 167 (4th Cir. 1994). The *Foster* court reasoned that "in this case the allegations of negligent misrepresentation are an effort to recover for injuries caused by a product without meeting the requirements the law imposes in products liability actions." *Id.* at 168. The court also concluded that, even if it considered the negligent misrepresentation claim on the merits under Maryland law, it would fail because "to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far." *Id.* at 171.

Based on *Foster*, a two-part analysis emerged. Courts first examine whether the applicable state law requires all claims brought by a generic consumer against a brand-name manufacturer to be treated as products liability claims. If not, courts next examine whether a brand-name manufacturer has a duty to the generic consumer under state common law principles. *See, e.g.*, *In re Darvocet*, 756 F.3d at 937 ("There are two analytical avenues by which a state's highest court would determine whether Plaintiffs have stated viable misrepresentation claims against Brand Manufacturers under applicable state law.")

A minority of courts, however, deviate from *Foster* for a number of reasons.[4] For example, the *Foster* court's understanding of generic drug manufacturers' responsibility for their labels was invalidated by *Mensing*. The *Foster* court noted that generic manufacturers "are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval[,]" *Foster*, 29 F.3d at 170, but the Supreme Court later held that generic manufacturers cannot strengthen or change their warnings and labels unilaterally because it would violate the federal "duty of sameness." *See Mensing*, 564 U.S. at 618–19, 131 S.Ct. 2567.

Following *Mensing*, the Supreme Court of California found that the unique circumstances of the prescription drug market in which, "one entity's misrepresentations about its own product foreseeably and legally contribute[ ] substantially to the harm caused by other entity's product" make warning label liability cases distinct from other products liability cases. *T.H. v. Novartis Pharms. Corp.*, 4 Cal.5th 145, 226 Cal.Rptr.3d 336, 407 P.3d 18, 39 (2017) (quotation omitted). The court observed that, "the plaintiffs' claim here is not that [the drug] is defectively designed or inherently dangerous. It is that [the drug]'s warning label failed to mention the risk [of side effects], and that Novartis was responsible for the deficient label. So the alleged fault here lies with Novartis, not with its generic competitors." *Id.*, 226 Cal.Rptr.3d 336, 407 P.3d at 33–34.

***5** Courts also distinguish between different states' tort laws, such as the California Supreme Court distinguishing California tort law from Maryland law as interpreted in *Foster*, because "California law does not conflate negligent misrepresentation and strict liability in the manner *Foster* believed was true of Maryland law." *Id.*, 226 Cal.Rptr.3d 336, 407 P.3d at 37. As such, the *Novartis* court decided that concerns about holding brand-name defendants liable for harm caused by a generic manufacturer's product were irrelevant, and permitted warning label liability claims to proceed under California tort law. *Id.*, 226 Cal.Rptr.3d

336, 407 P.3d at 37–40. [5] Additionally, the court found that "California law places greater weight on foreseeability in the duty analysis" than Maryland law, and "[does] not narrowly construe the kinds of relationships that must exist" to impose a duty to prevent injuries from a defendant's own conduct. *Id.*, 226 Cal.Rptr.3d 336, 407 P.3d at 38–39. The court therefore found a duty existed between the brand-name manufacturer and a generic consumer injured by the brand-name manufacturer's inadequate labeling. *Id.*

The Supreme Court of Alabama also distinguished its common law from Maryland's, and concluded that generic consumers could pursue claims for fraud and misrepresentation in the warning label against brand-name manufacturers. *See Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676-77 (Ala. 2014). Shortly after the *Weeks* decision, however, the Alabama legislature superseded the decision by statute, to require that, "regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based[.]" *Forest Labs., LLC v. Feheley*, 296 So. 3d 302, 312–13 (Ala. 2019) (quoting Ala. Code § 6-5-530(a) (2015)).

The Court recognizes that the cases rejecting *Foster* and permitting generic consumers to assert claims against brand-name manufacturers for faulty labeling represent a minority view, since courts more often find that the operative state law does not support warning label liability claims. However, the Court finds that whether Butkiewicz's claims are viable relies solely on the contours of Illinois law. With this in mind, the Court turns to Illinois law.

C. Illinois Law

Irrespective of decisions in other jurisdictions, the Court is obligated to apply Illinois law. *See Blankenship v. USA Truck, Inc.*, 601 F.3d 852, 856–57 (8th Cir. 2010) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78, 58 S.Ct. 817, 82 L.Ed. 1188 (1938)). The Illinois Supreme Court has not directly addressed pharmaceutical warning label liability claims brought by a generic consumer against a brand-name manufacturer. "When there is no state supreme court case directly on point," the role of a federal court sitting in diversity jurisdiction "is to predict how the state supreme court would rule if faced with the same issue[.]" *N. Oil & Gas, Inc. v. EOG Res., Inc.*, 970 F.3d 889, 892 (8th Cir. 2020) (quoting *Blankenship,* 601 F.3d at 856).

1. *Smith v. Eli Lilly*

***6** Although the Illinois Supreme Court has not addressed whether brand-name drug manufacturers are subject to warning label liability, Defendants argue that such claims are precluded by *Smith v. Eli Lilly*, 137 Ill.2d 222, 148 Ill.Dec. 22, 560 N.E.2d 324 (Ill. 1990). In *Smith*, the plaintiff faced the issue of indeterminate tortfeasors because she could not identify the actual manufacturer of the drug ingested. *Id.*, 148 Ill.Dec. 22, 560 N.E.2d at 326. Instead, the plaintiff argued that each defendant's respective market share should serve as a proxy for causation. *Id.* The Illinois Supreme Court rejected this "market share liability" theory because "[a] fundamental principle of tort law is that the plaintiff has the burden of proving by a preponderance of the evidence that the defendant caused the complained-of harm or injury; mere conjecture or speculation is insufficient proof.... Likewise, to recover under strict liability the plaintiff must establish some causal relationship between the defendant and the injury-producing agent." *Id.*, 148 Ill.Dec. 22, 560 N.E.2d at 328. In other words, the "identification element of causation" limits the scope of potential liability in products liability cases. *Id.*, 148 Ill.Dec. 22, 560 N.E.2d at 329.

Defendants posit that the *Smith* plaintiff's theory of market share liability is functionally identical to Butkiewicz's theory of Defendants' warning label liability, and therefore his claims must fail for lack of product identification. Contrary to Defendants' position, it is difficult to see how the two theories of liability are functionally identical. The plaintiff in *Smith* had to rely on market share liability because she could not determine which entity was responsible for the harmful conduct due to the passage of time and other factors such as poor record-keeping. Here, Butkiewicz knows exactly which entity is responsible for the allegedly harmful conduct: the Bayer Defendants. Defendants created the label that allegedly caused Butkiewicz's doctor to prescribe ciprofloxacin. Butkiewicz has identified the defendant and duty owed: Defendants' exclusive responsibility for the warnings that must accompany both brand-name Cipro and generic ciprofloxacin.

Furthermore, *Smith*'s duty-limiting principle does not apply to Butkiewicz's claims. The *Smith* court held that "[e]ach manufacturer owes a duty to plaintiffs who will use its drug or be injured by it. However, the duty is not so broad as to extend to anyone who uses the type of drug manufactured by a defendant[.]" *Id.*, 148 Ill.Dec. 22, 560 N.E.2d at 343 (citation omitted). *Smith* involved a plaintiff alleging liability based upon physiological harm caused by ingesting the defendants' drug. Here, Butkiewicz does not seek to hold Defendants liable because he used the type of drug they manufacture. Rather, he seeks to hold Defendants liable because he relied on a warning label that Defendants undisputedly wrote—even if that label was affixed to a different product. As such, the Court finds that *Smith* does not preclude Butkiewicz's warning label claims.

The Northern District of Illinois, considering allegations similar to Butkiewicz's, agreed that *Smith* presents a materially different fact pattern under Illinois law. In *Dolin v. SmithKline Beecham Corp.* the plaintiff filed a lawsuit against defendant GlaxoSmithKline ("GSK"), the manufacturer of brand name Paxil, for failure to warn of a risk of suicide after her late-husband was prescribed Paxil but received the generic equivalent, paroxetine. 62 F. Supp. 3d 705, 709–10 (N.D. Ill. 2014), *rev'd on other grounds sub. nom., Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803 (7th Cir. 2018).[6] The *Dolin* court rejected GSK's argument that *Smith* required dismissal, saying that, although "[t]aken out of context, language in product identification cases like *Smith* ... may well appear to support GSK's argument," the problem of indeterminate tortfeasors was not at issue in the case at hand. *Id.* at 718. Therefore, "to suggest that the question actually raised here is simply whether GSK may be held liable for injuries caused by a product that [the generic company] manufactured is incomplete and misleading." *Id.* Rather, the question is "whether GSK, though not the pill's manufacturer, may nevertheless be held liable for tortious conduct that was extrinsic to the manufacturing process and that contributed to Plaintiff's injury." *Id.*

***7** Defendants urge the Court to disregard *Dolin* and instead adopt the Sixth Circuit's analysis of Illinois law. The Sixth Circuit suggested that generics warning label claims brought against brand-name manufacturers would fail under Illinois law for lack of product identification pursuant to *Smith*. *See In re Darvocet*, 756 F.3d at 944 (citing *Smith*, 148 Ill.Dec. 22, 560 N.E.2d at 328).[7]

The Court declines. The Sixth Circuit and Defendants misunderstand the type of injury a generic consumer can attribute to a brand-name manufacturer through warning label liability. Butkiewicz, like the plaintiff in *Dolin*, did "not [bring] suit against [the drug company] for tortious conduct committed strictly as a manufacturer of products." *Dolin*, 62 F. Supp. 3d at 713. Rather, Butkiewicz seeks to recover for injuries related to ciprofloxacin's warning label and product information, authored by Defendants, which failed to inform him and his prescribing physician about the risks of peripheral neuropathy. That Defendants "did not manufacturer the pill [Mr. Butkiewicz] ingested is largely immaterial on this point. A problem with [ciprofloxacin]'s warning label and design will impact the name-brand version ... and any generic versions of the drug equally." *Id.* at 715. Thus, fault for any alleged injury related to ciprofloxacin's label can be attributed to Defendants. *Accord Novartis*, 226 Cal.Rptr.3d 336, 407 P.3d at 34–35.

Because the Court finds that *Smith* does not preclude warning label liability claims against Defendants, the Court examines whether the Illinois Supreme Court would dismiss or permit Butkiewicz's claims following the two-part analysis from *Foster* noted above: first, whether Illinois law would require his negligence and fraud claims to be treated as strict product liability claims, and second, if those claims are distinct, whether Defendants owed a duty to Butkiewicz.

2. Whether Negligence and Fraud Claims Are Distinct from Product Liability Claims

As part of its analysis of *Smith*, the Sixth Circuit noted that, "[w]hile Illinois does not have a product liability statute, its case law indicates that Plaintiffs' misrepresentation claims would be construed as product liability claims and fail for lack of product identification" since Illinois law requires a plaintiff to "identify the supplier of the product and establish a causal connection between the injury and the product." *In re Darvocet*, 756 F.3d at 944 (quoting *York v. Lunkes*, 189 Ill.App.3d 689, 136 Ill.Dec. 954, 545 N.E.2d 478, 480 (1989)). But a closer look at Illinois case law, including cases the Sixth Circuit relied on, reveals that Illinois law does not require the Court to construe Butkiewicz's claims as products liability claims.

First, the Sixth Circuit relied on *Smith v. Eli Lilly* and *York v. Lunkes* to conclude that Illinois law requires that warning label claims be treated as de facto product liability claims. *In re Darvocet*, at 756 F.3d at 944. Yet, like *Smith, York* is a case in which the plaintiff could not identify the precise wrongdoer—an issue of indeterminate tortfeasors—which is not an issue currently before the Court, and therefore these two Illinois decisions do not compel the Court to construe Butkiewicz's negligence and fraud claims as products liability claims. *Cf. Dolin*, 62 F. Supp. 3d at 716–17 (noting that generic warning label claims and indeterminate tortfeasor claims involve two "facially similar, but fundamentally distinct" tort issues).

***8** Moreover, the Illinois Supreme Court has recognized that injuries caused by use of a product and injuries caused by faulty information provided with the product are legally distinct. For example, in *Board of Education of City of Chicago v. A, C and S, Inc.*, the Supreme Court of Illinois first addressed products liability claims, and then separately analyzed claims for negligent and fraudulent misrepresentation. 131 Ill.2d 428, 137 Ill.Dec. 635, 546 N.E.2d 580, 585–95 (1989). The court explained that negligent misrepresentation liability "extends to any defendant 'who, in the course of an activity which is in furtherance of his own interests, undertakes to give information to another, and knows or should realize that the safety of the person of others may depend upon the accuracy of the information.' " *Id.*, 137 Ill.Dec. 635, 546 N.E.2d at 593 (quoting Restatement (Second) of Torts § 311, Explanatory Notes, cmt. b, at 106 (1965)).

Although *Board of Education* was decided outside the pharmaceutical drug context, it is nonetheless indicative that, in a product-related case, Illinois law (1) does not require negligent misrepresentation claims to be treated as de facto products liability claims, and (2) analyzes negligent misrepresentation claims based on a defendant's conduct in providing information about a product, not just their conduct in manufacturing or distributing the product.

As such, the Court finds that Illinois law does not preclude Butkiewicz's claims because it does not require that warning label liability claims be construed as products liability claims, and Butkiewicz's claims need not fail because Defendants did not manufacture the pill he ingested. Thus, Butkiewicz may assert claims specifically related to injuries caused by Defendants' labeling separately from injuries caused by the drug itself. Accordingly, the Court will proceed to part two of the warning label liability analysis: whether Defendants owe a duty of care to a generic consumer like Butkiewicz when creating the label for Cipro and ciprofloxacin.

D. Defendants' Duty to Generic Consumers

The "touchstone of [the Court's] duty analysis is to ask whether a plaintiff and a defendant stood in such a relationship to one another that [Illinois] law imposed upon the defendant an obligation of reasonable conduct for the benefit of the plaintiff." *Simpkins v. CSX Transp., Inc.*, 358 Ill.Dec. 613, 965 N.E.2d 1092, 1097 (Ill. 2012) (emphasis omitted). An analysis of such a relationship involves four factors: (1) the reasonable foreseeability of the injury, (2) the likelihood of the injury, (3) the magnitude of the burden of guarding against the injury, and (4) the consequences of placing that burden on the defendant. *Id.* Here, the foreseeability, burden, and consequences of the duty are the most pertinent factors. [8]

A generic drug manufacturer is required to use the label and product information created by the brand-name manufacturer. *See Mensing*, 564 U.S. at 618, 131 S.Ct. 2567. It is therefore foreseeable that misconduct by Defendants with respect to the warning label could result in injury to a consumer who uses the generic drug.

The *In re Darvocet* court, by contrast, concluded that the Illinois Supreme Court would not find that brand-name manufacturers owe generic consumers a duty because "generic consumers' injuries are not the foreseeable result of the brand manufacturer's conduct, but of the laws over which the brand manufacturers have no control." 756 F.3d at 944. It is true that Defendants are responsible for ciprofloxacin's warning label only by virtue of federal law. Yet, if Defendants' conduct when creating the warning label is negligent or fraudulent, then injuries from the label, whether it is affixed to Cipro or ciprofloxacin, are a foreseeable result of their conduct with respect to labeling. Because Illinois law does not require a direct relationship between the parties for a duty to exist, the Court finds that an injury to generic consumers is sufficiently foreseeably. *See Simpkins*, 358 Ill.Dec.

613, 965 N.E.2d at 1097 (finding that a "direct relationship" between parties "is not an additional requirement to establishing a duty"); *accord Novartis*, 226 Cal.Rptr.3d 336, 407 P.3d at 37–38.

***9** The burden of Defendants' duty to guard against injury to generic consumers from their labeling, and the consequences of that burden, are minimal. Defendants' duty to Butkiewicz or any other generic consumer only requires that they exercise the same level of care as when labeling their brand-name drugs. Thus, the consequence is merely reinforcement of Defendants' pre-existing duty to provide adequate warning labels. So long as warning label liability claims are restricted to injuries caused by a deficient label, imposing a duty does not present grave consequences for Defendants. Rather, permitting Butkiewicz to assert negligence and fraud claims against Defendants "simply allows [the plaintiff] to attempt to recover for deficiencies in [the drug's] label from the one entity, under federal law, that has unilateral ability to strengthen the label." *Garner v. Johnson & Johnson*, No. 16-1494, 2017 WL 6945335 at *7 (C.D. Ill. Sept. 6, 2017).

The Court concludes that, under Illinois law, Defendants had a duty to Butkiewicz when creating the ciprofloxacin warning label because he foreseeably relied on their warning label, even though it was affixed to a product Defendants did not manufacture. However, this is a limited duty because the relationship between Defendants and Butkiewicz only relates to ciprofloxacin's label. Thus, any recovery shall be fashioned accordingly to redress only injuries caused by the label. The Court therefore proceeds to analyze Butkiewicz's specific claims.

E. Butkiewicz's Claims

1. Strict Liability and Products Liability – Failure to Warn

As to Butkiewicz's strict liability and product liability – failure to warn claims, the Court agrees with Defendants that Butkiewicz cannot state a claim against Defendants. Under Illinois law, to recover based on strict liability in a products liability action, a plaintiff must allege that "the injury complained of resulted from a condition of the product, that the condition was unreasonably dangerous, and that it existed at the time the product left the manufacturer's control." *Mikolajczyk v. Ford Motor Co.*, 231 Ill.2d 516, 327 Ill.Dec. 1, 901 N.E.2d 329, 335 (2008). Strict liability may only be imposed against entities in the "distributive chain" for a product, such as manufacturers, distributors, and retailers. *See Dolin*, 62 F. Supp. 3d at 721 (citing *Hammond v. N. Am. Asbestos Corp.*, 97 Ill.2d 195, 73 Ill.Dec. 350, 454 N.E.2d 210, 216 (1983)). Because Defendants are not in the distributive chain for generic ciprofloxacin, Butkiewicz has failed to state a strict liability claim.

Likewise, the Court will dismiss Butkiewicz's claim for product liability – failure to warn. It appears that Butkiewicz's failure to warn claim is a negligent products liability claim. [9] "[A] plaintiff may plead a product liability negligence claim by pointing to a way in which the product was unreasonably dangerous and defendant failed to warn of its dangerous propensity." *Garner*, 2017 WL 6945335, at *8 (quotation omitted). [10] In other words, like a strict liability claim, a negligent products liability claim requires an analysis of the condition of the product. As such, the Court finds that permitting Butkiewicz's product liability – failure to warn claim to proceed would run afoul of product liability principles because Defendants are outside the chain of distribution for ciprofloxacin. [11] The Court will therefore dismiss Butkiewicz's claim for product liability – failure to warn.

2. Breach of Express and Implied Warranty

***10** To state a claim for breach of express warranty under Illinois law, "the terms of the express warranty must be stated or attached to the complaint, and failure to do so renders the claim invalid." *Bd. of Educ.*, 137 Ill.Dec. 635, 546 N.E.2d at 595 (citations omitted). Illinois law treats express warranty claims as contract claims and typically requires privity between the parties for viable breach of express warranty claims. *See Collins Co. v. Carboline Co.*, 125 Ill.2d 498, 127 Ill.Dec. 5, 532 N.E.2d 834, 841–42 (1988). The language of the ciprofloxacin warning label and product information, the express warranty at issue, is included in the MDL Master Complaint. However, because the parties are not in privity, the Court finds that Butkiewicz has failed to state a claim for breach of express warranty.

Butkiewicz also claims breach of the implied warranty of merchantability. Under Illinois law, implied breach of warranty claims are treated as contract claims and require privity between the parties. *Szajna v. General Motors Corp.*, 115 Ill.2d 294, 104 Ill.Dec. 898, 503 N.E.2d 760, 766–67 (1986). There is no contract between Butkiewicz and Defendants, and Defendants did not sell the ciprofloxacin to Butkiewicz. Accordingly, the Court finds that Butkiewicz cannot state a claim for breach of the implied warranty of merchantability.

3. Negligence and Negligent Misrepresentation

Unlike his products liability claims, Butkiewicz's negligence and negligent misrepresentation claims do not require Defendants to be in the chain of distribution for ciprofloxacin. Rather, the claims turn on whether Defendants had a duty to Butkiewicz under Illinois law to guard against injury from the information Defendants provided about ciprofloxacin. Because the Court finds that Defendants did have a duty to Butkiewicz, the Court will analyze whether Butkiewicz has stated a negligence claim. To state a negligence claim, Butkiewicz must allege facts that establish a breach of a duty of care owed by Defendants and an injury proximately caused by that breach. *See Simpkins*, 358 Ill.Dec. 613, 965 N.E.2d at 1096.

Butkiewicz alleges that Defendants had a duty to adequately inform him and his physician of known side effects from ciprofloxacin. Yet, despite knowing of the risk of peripheral neuropathy, Defendants recklessly concealed the information from Butkiewicz by omitting it from the warning label for Cipro and ciprofloxacin, thereby breaching their duty to disclose. Because Butkiewicz relied on the ciprofloxacin warning label, he failed to recognize neuropathy symptoms as a side effect of ciprofloxacin, resulting in injury caused by Defendants' breach. Accepting the factual allegations as true, the Court finds that Butkiewicz states a claim for negligence related to the warning labels on ciprofloxacin.

To state a claim for negligent misrepresentation under Illinois law, a plaintiff must show: (1) a false statement of material fact; (2) negligence on the part of the defendant in ascertaining the truth; (3) intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statements; and (5) damage to the other party resulting from such reliance. *See Bd. of Educ.*, 137 Ill.Dec. 635, 546 N.E.2d at 591.

Butkiewicz alleges that Defendants made materially false statements about the severity and frequency of the onset of peripheral neuropathy from ciprofloxacin by, among other things, paying consultants to falsely tout its benefits and downplay its risks in scientific literature. Butkiewicz alleges Defendants should have known through due care that the statements were false, Defendants acted recklessly and intentionally, that Butkiewicz and other plaintiffs relied on Defendants' statements, and Butkiewicz was injured. Therefore, the Court finds that Butkiewicz has also stated a claim for negligent misrepresentation.

4. Fraud and Fraudulent Concealment

***11** Under Illinois law, to state a claim for common law fraud, a plaintiff must allege that defendants (1) made a false statement of material fact, (2) knew the statement was false, and (3) intended that the statement induce the plaintiff to act; and that the plaintiff (4) relied on the truth of the statement, and (5) suffered damages resulting from reliance on the statement. *Connick v. Suzuki Motor Co.*, 174 Ill.2d 482, 221 Ill.Dec. 389, 675 N.E.2d 584, 591 (1996). For fraudulent concealment, a plaintiff must allege that a defendant concealed a material fact when they were under a duty to disclose that fact to the plaintiff. *Id.*, 221 Ill.Dec. 389, 675 N.E.2d at 593. A duty to disclose could be based on a fiduciary or confidential relationship, or because the defendant otherwise is in a position of influence of superiority over the plaintiff. *Id.*

As discussed above, Illinois law does not compel the Court to construe all of Butkiewicz's claims as product liability claims, and Defendants have a duty to Butkiewicz to guard against injury from reliance on the ciprofloxacin warning label. As such, the Court finds that claims for fraud and fraudulent concealment related to the warning label are cognizable and turns to the sufficiency of the allegations under Federal Rule of Civil Procedure 9(b). *Cf. Garner*, 2017 WL 6945335, at *8 (dismissing fraud and fraudulent concealment claims because the plaintiff did not plead them with sufficient particularity).

Rule 9(b) requires fraud-based claims to be pleaded with particularity. Fed. R. Civ. P. 9(b). The "plaintiff must specifically allege the circumstances constituting fraud, including such matters as the time, place and contents of false representations[.]" *Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 920 (8th Cir. 2001) (cleaned up). In other words, "the complaint must identify the who, what, where, when, and how of the alleged fraud." *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006) (quotation omitted).

Butkiewicz, through the MDL Master Complaint, provides detailed allegations about the contents and timing of Defendants' allegedly fraudulent conduct, such as efforts to downplay the significance of a study about ciprofloxacin's serious side effects in 2001, identifies, by name, paid medical consultants and Bayer employees who allegedly made false statements and representations and quotes their statements, and explains how and why Defendants were aware of risks from the drug but chose to aggressively market it nonetheless. Therefore, the Court finds that Butkiewicz has plausibly stated claims for fraud and fraudulent concealment.

5. Illinois Consumer Protection

To state a claim for a violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, Ill. Comp. Stat. 505 et seq., a plaintiff must allege "(1) a deceptive act or practice by the defendant, (2) the defendant's intent that the plaintiff rely on the deception, (3) the occurrence of the deception in the course of conduct involving trade or commerce, and (4) actual damage to the plaintiff (5) proximately caused by the deception." *Avery v. State Farm Mut. Auto. Ins. Co.*, 216 Ill.2d 100, 296 Ill.Dec. 448, 835 N.E.2d 801, 850 (2005).

Butkiewicz's allegations plausibly satisfy the five elements by stating that Defendants deceived consumers by covering up information about ciprofloxacin's serious side effects by failing to include a warning about peripheral neuropathy on the label, Defendants intended consumers and physicians to rely on their misrepresentations, and Butkiewicz relied on the inadequate warning label, leading to undiagnosed peripheral neuropathy. Therefore, the Court finds that Butkiewicz has plausibly stated a claim that Defendants violated Illinois consumer protection law.

CONCLUSION

Butkiewicz seeks to redress injuries caused by the deficient warning label on ciprofloxacin, which Defendants authored. Under Illinois law, the Court is not required to treat Butkiewicz's negligence, negligent misrepresentation, fraud, fraudulent concealment, and consumer protection claims as product liability claims, and these claims therefore do not fail simply because Defendants did not manufacture the drug Butkiewicz consumed. Defendants had a duty to Butkiewicz to exercise reasonable care in the course of creating the warning label for generic ciprofloxacin. The Court acknowledges that similar claims have gained little traction in other jurisdictions. However, the Court finds that warning label claims against a brand-name drug manufacturer are viable pursuant to Illinois law, insofar as a generic consumer seeks to recover for injuries caused by an allegedly deficient label.

ORDER

***12** Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Defendants' Motion to Dismiss [Docket No. 34] is **GRANTED** as to Counts I, II, IV, and V, and **DENIED** as to all other Counts. Counts I, II, IV, and V are **DISMISSED with prejudice.**

All Citations

--- F.Supp.3d ----, 2021 WL 396819

Footnotes

1 Butkiewicz initially alleged that he used brand-name Cipro, (*see* Compl. ¶¶ 1–2, June 4, 2019, Docket No. 1), but has since clarified that he used generic ciprofloxacin, (*see* 2nd Am. Compl. ¶ 9, Apr. 27, 2020, Docket No. 30.) The Court therefore treats all of Butkiewicz's allegations as generics-related claims. Additionally, the Court considers allegations from Butkiewicz's Individual Complaint in tandem with allegations in the MDL Master Complaint and Short Form Complaint, since cases consolidated for multi-district litigation pre-trial proceedings retain their separate identities. *See Gelboim v. Bank of America Corp.*, 574 U.S. 405, 413, 135 S.Ct. 897, 190 L.Ed.2d 789 (2015).

2 The MDL Master Complaint, incorporated by reference in Butkiewicz's Amended MDL Short Form Complaint, alleges Defendants may be liable for generics-related claims because "[i]n *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 720–21 (N.D. Ill. 2014), the court held that under Illinois common law, a brand-name manufacturer owes a duty of care to the generic consumer." (MDL Master Compl. ¶ 113.)

3 *See, e.g.*, *Strayhorn v. Wyeth Pharms.*, 737 F.3d 378, 401 (6th Cir. 2013) (noting *Foster* as the "leading case on this issue"); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092 (8th Cir. 2013) (citing *Foster* to support rejecting the existence of a duty between brand-name manufacturer and generic consumer); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1284–85 (10th Cir. 2013) ("Since *Foster* was decided, every federal court to address this issue ... has consistently followed.").

4 *See, e.g.*, *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 718 (N.D. Ill. 2014) (explaining that the *Foster* court incorrectly "analyzed the complaint as though it presented an indeterminate tortfeasor problem"); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 707 (D. Vt. 2010) (distinguishing cases that agreed with *Foster* on the basis that many had statutes defining the scope of permissible actions against manufacturers, whereas "Vermont has not enacted such a statute"); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 110, 85 Cal.Rptr.3d 299 (2008) (describing "countervailing factors" that warrant a different policy analysis than *Foster*).

5 The California Supreme Court also distinguished its relationship to California law from the Fourth Circuit's relationship to Maryland law in *Foster*, noting that federal courts sitting in diversity jurisdiction are "extremely cautious" about recognizing innovative theories under state law. *Novartis*, 226 Cal.Rptr.3d 336, 407 P.3d at 38. Here, because the Court is sitting in diversity jurisdiction, Defendants assert that "[w]hen given a choice between an interpretation of Illinois law which reasonably restricts liability, and one which greatly expands liability, [the Court] should choose the narrower and more reasonable path (at least until the Illinois Supreme Court tells [the Court] differently)." *Todd v. Societe Bic, S.A.*, 21 F.3d 1402, 1412 (7th Cir. 1994).

However, based on the existing warning label cases under Illinois law and Illinois products liability and tort precedent as discussed below, the Court's decision does not greatly expand liability, it merely applies Illinois law. Additionally, the Court notes that cases such as *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705 (N.D. Ill. 2014) already opened the door to Butkiewicz's claims, as evidenced by the inclusion of generics-related claims under Illinois law in this MDL. Illinois tort law has developed to redress all sorts of injuries, and the Court finds that this scenario, although unique, is no exception.

6 The Seventh Circuit dismissed the case on preemption grounds because the warning which the plaintiff claimed GSK should have included was previously rejected by the FDA, so GSK could not simultaneously comply with state law, requiring it to strengthen the label, and federal law, which rejected the strengthened version. *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 813–16 (7th Cir. 2018). The Seventh Circuit declined to comment on the district court's analysis on the duty question because the preemption issue was decisive. *Id.*

7 *See also In re: Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 2924, —— F.Supp.3d ——, ——, 2020 WL 7866660, at *19–20 (S.D. Fla. Dec. 31, 2020) (finding that the Sixth Circuit's holding in *In re Darvocet* is "sound and more persuasive" than *Dolin*). Because the Southern District of Florida relied solely on the Sixth Circuit's analysis rather than examining the underlying Illinois caselaw, the recent *In re Zantac* decision does not affect the Court's analysis of and disagreement with *In re Darvocet* as described herein.

8 As to the second element, since the labels on brand-name and generic drugs must be the same at all times, *Mensing*, 564 U.S. at 618–19, 131 S.Ct. 2567, the likelihood of injury based on the warning label is the same for consumers of brand-name Cipro as for consumers of generic ciprofloxacin. Thus, the likelihood of injury is neutral as to whether the brand-name manufacturer has a duty to generic consumers who rely on their label.

9 Illinois recognizes both negligent and strict products liability, which are differentiated by whether the focus is on the condition of a product for strict liability or the condition of a product plus a defendant's fault for negligence. *See Calles v. Scripto-Tokai Corp.*, 224 Ill.2d 247, 309 Ill.Dec. 383, 864 N.E.2d 249, 263–64 (2007).

10 *See also Great N. Ins. Co. v. Amazon.com, Inc.*, No. 19-684, 2019 WL 3935038, at *2 (N.D. Ill. Aug. 20, 2019) ("[A] negligent failure to warn claim is viable only if the defendant knew or should have known of the danger 'at the time the product left its control.' ") (quoting *Modelski v. Navistar Int'l Transp. Corp.*, 302 Ill.App.3d 879, 236 Ill.Dec. 394, 707 N.E.2d 239, 246 (1999)).

11 The Court notes that, on this point, its conclusion differs from the *Dolin* court's holding. *See Dolin*, 62 F. Supp. 3d at 720–21. The Court finds that the products liability principles which the *Dolin* court itself relied on to dismiss strict liability claims should also apply to negligent product liability claims. Although negligent product liability claims depend on a defendant's duty and conduct, and are analyzed within the framework of common law negligence, they also depend on the condition of the product. *See, e.g.*, *Rose v. Vanity Fair Brands, LP*, No. 13-167, 2013 WL 1752705, at *3 (N.D. Ill. Apr. 23, 2013) (citing *Calles*, 309 Ill.Dec. 383, 864 N.E.2d at 263 and *Blue v. Environmental Engineering, Inc.*, 215 Ill.2d 78, 293 Ill.Dec. 630, 828 N.E.2d 1128, 1141 (2005)). As the *Dolin* court noted, the warning label created by Defendants is not a product; ciprofloxacin is the product. *See Dolin*, 62 F. Supp. 3d at 721–22. Therefore, because Defendants are outside the distributive chain, the Court finds that they cannot be liable for negligent products liability, so long as the claim depends in part on the condition of a product Defendants did not manufacture or distribute.

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2017 WL 6945335
Only the Westlaw citation is currently available.
United States District Court, C.D. Illinois,
Peoria Division.

Tracy GARNER, Plaintiff,
v.
JOHNSON & JOHNSON, JANSSEN RESEARCH AND DEVELOPMENT LLC f/k/a Johnson and Johnson Pharmaceutical Research and Development, LLC, Ortho-McNeil-Janssen Pharmaceuticals Inc., and Zydus Pharmaceuticals (USA) Inc., a Div. of Cadila Healthcare, Defendants.

Case No. 1:16-cv-01494-SLD-JEH
|
Signed September 06, 2017

Attorneys and Law Firms

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ORDER

SARA DARROW, UNITED STATES DISTRICT JUDGE

***1** Before the Court are a Motion to Dismiss for Failure to State a Claim, ECF No. 10, by Defendants Johnson & Johnson, Janssen Research & Development LLC, and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (collectively, "Janssen") and an Amended Motion to Dismiss, ECF No. 17, by Defendant Zydus Pharmaceutical (USA), Inc. ("Zydus"). All Defendants seek dismissal of the Amended Complaint, ECF No. 3, by Plaintiff Tracy Garner.

BACKGROUND [1]

On December 24, 2014, Plaintiff Garner, a citizen of Knox County, Illinois, was prescribed generic levofloxacin, a strong fluoroquinolone antibiotic, to treat a urinary tract infection. Garner took the drug, manufactured by Zydus, in its prescribed dosage. At some point thereafter, Garner began to experience adverse reactions and suspected they were connected to her use of the levofloxacin: a non-exhaustive list of those reactions included peripheral neuropathy, [2] fluoroquinolone toxicity, mental status changes, chronic pain, fatigue, gastrointestinal problems, tinnitus, and skin changes.

The United States Food and Drug Administration ("FDA") originally approved levofloxacin in 1996 under the brand name "Levaquin," as it was originally created, manufactured, and marketed by Janssen. Levaquin has been widely used across the world, at one point ranking first in the world for prescribed antibiotics. The Ortho-McNeil website [3] stated about Levaquin that it "has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections." Compl. ¶ 35. The FDA approved levofloxacin for generic manufacture and sale in the United States in 2011. At that point, pharmaceutical company Zydus began to manufacture a generic form of levofloxacin that contained the same active ingredient as, and was the

bioequivalent and therapeutic equivalent of, Levaquin. As required by the FDA, Zydus adopted warning labels for levofloxacin identical to those used by Janssen.

Plaintiff alleges that scientific evidence, beginning in 1992, showed a link between levofloxacin and a heightened risk of long term and irreversible peripheral neuropathy and other medical conditions, including some of the ones experienced by Garner. In 2002 and 2003, reports to the FDA's Adverse Event Reporting System showed that other users of fluoroquinolones had developed long-lasting peripheral neuropathy. In 2013, the FDA drafted a memo regarding the connection between disabling peripheral neuropathy and fluoroquinolone use that linked the drug to ALS, Alzheimer's, and Parkinson's disease. That memo was never made public. A January 2014 medical paper further questioned the risk-benefit analysis of using fluoroquinolones and linked fluoroquinolones to peripheral neuropathy. A Citizen's Petition filed with the FDA on September 8, 2014 chronicled adverse events reported after patients took fluoroquinolones, including disorientation, agitation, depression, attention deficit, panic attacks, memory impairment, and nervousness.

***2** Garner alleges that "Defendants" (she does not ascribe the action to any one defendant in particular) failed to heed these "safety signals," despite public representations by Johnson & Johnson that it monitors the "safety and effectiveness" of medications it produces, in cooperation with the FDA. Instead, Defendants conveyed false information about the drug's safety.

On November 5, 2015, almost a year after Garner was prescribed levofloxacin, the FDA Advisory Committee held a meeting at which it considered the risk-benefit analysis of fluoroquinolone antibacterial drugs. An FDA employee stated that the FDA became aware of the danger of fluoroquinolones in causing multi-system disability as early as 2013, but it had not suggested any changes to the levofloxacin safety warning label. The Adverse Event Reporting System now identifies fluoroquinolone adverse reactions involving the neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, and cardiovascular systems. These reactions are now identified by a new term, "Fluoroquinolone-Associated Disability" ("FQAD"). As of May 2016, the FDA strongly advises against the use of fluoroquinolones for the treatment of simple infections including sinusitis, bronchitis, and urinary tract infections, stating that they should be used only for patients who do not have other treatment options.

Garner filed suit on December 22, 2016, alleging that the Court could exercise diversity jurisdiction under 42 U.S.C. § 1331. Garner is a resident and citizen of Illinois. Johnson & Johnson, Janssen Research & Development LLC ("Janssen R&D"), and Zydus are all New Jersey corporations with principal places of business in New Jersey, except for Janssen R&D, which has its principal place of business in Pennsylvania. Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho-McNeil") is a Delaware corporation with its principal place of business in New Jersey. Against Defendant Janssen, Garner alleges five counts including (I) negligence, (II) negligent misrepresentation, (III) fraud, (IV) fraudulent concealment, and (V) product liability negligence. Against Zydus, Garner alleges eight counts, including: (VI) negligence, (VII) negligent misrepresentation, (VIII) fraud, (IX) fraudulent concealment, (X) product liability, (XI) breach of express warranty of merchantability, (XII) breach of implied warranty of merchantability, and (XIII) strict liability. Janssen and Zydus filed motions to dismiss the amended complaint, pursuant to Federal Rule of Civil Procedure 12(b)(6). *See* Janssen Mot. Dismiss, ECF No. 10; Zydus Am. Mot. Dismiss, ECF No. 17. Janssen admits it researched, developed, and sold Levaquin but argues that because Garner took the generic form of levofloxacin, which it did not manufacture, it cannot be liable for her injury. Janssen Mot. Dismiss 2–4. Janssen argues that the Court should reject the theory of liability, known as innovator liability, which would impose a duty of care on Janssen to Garner. Zydus puts forth that it cannot be liable either, arguing that since the warning labels on generic drugs are required by law to mirror the brand name label, Garner's claim against Zydus is preempted by federal law. Zydus Mot. Dismiss 3.

DISCUSSION

I. Legal Standard on a Motion to Dismiss

A court will dismiss a complaint if it does not state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). Federal Rule of Civil Procedure 8(a) requires a plaintiff to provide "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a). The pleader's claim must be facially plausible, meaning that the factual allegations

allow the court to draw a "reasonable inference" that the purported misconduct occurred. *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). This means that a complaint must provide "allegations that raise a right to relief above the speculative level." *Tamayo v. Blagojevich*, 526 F.3d 1074, 1084 (7th Cir. 2008). A complaint must also describe its claims in sufficient detail to give a defendant "fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)) (alteration in *Bell Atlantic*). A court may dismiss a complaint "on the basis of a dispositive issue of law." *Neitzke v. Williams*, 490 U.S. 319, 327 (1989).

II. Analysis

A. The Hatch-Waxman Act

***3** The holders of patents for brand name drugs must go through a lengthy approval process with the FDA, often including extensive and expensive clinical trials and testing, before a new drug can hit the market. *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2470–71 (2013). Mindful of the rigor required for the submission of a new-drug application for brand name drugs ("NDA"), Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, which amended the Food, Drug, and Cosmetics Act ("FDCA"). 21 U.S.C. § 355. In the interest of making innovative drugs available in generic (and cheaper) form on an expedited basis, the Hatch-Waxman Act allows generic drug manufacturers to use an abbreviated new drug application process ("ANDA"). To make it to market, the generic drug must establish it: (1) is the chemical equivalent of the brand name drug, including the identification of active ingredients, route of administration, dosage form, and strength, 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii); (2) is the bioequivalent of the brand name drug, such that it has the same "rate and extent of absorption," 21 U.S.C. §§ 355(j)(2)(A)(iv), (8); and (3) has the identical FDA-approved label of the brand name drug, § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7).

Under the Hatch-Waxman regime, a brand-name manufacturer is "responsible for the accuracy and adequacy of its label," and a manufacturer of generic drugs is "responsible for ensuring that its warning label is the same as the brand name's." *PLIVA, Inc. v. Mensing*, 564. S. 604, 613 (2011). Federal drug regulations prevent generic manufacturers from independently modifying the label at any time while the drug is on the market. 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10).

B. Claims Against Zydus

Garner brings eight counts against Zydus: (VI) negligence, (VII) negligent misrepresentation, (VIII) fraud, (IX) fraudulent concealment, (X) product liability, (XI) breach of express warranty, (XII) breach of implied warranty of merchantability, and (XIII) strict liability. *See* Compl. 24–38.

The Supreme Court, in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013), examined whether failure to warn and design defect claims against generic drug manufacturers are preempted by the FDCA because of the labeling identity requirement, answering that inquiry affirmatively. In *Mensing*, the Court determined that "federal drug regulations applicable to generic drug manufacturers directly conflict with and thus preempt ... state law claims" that are based on the manufacturer's alleged failure to provide adequate warning labels." *Mensing*, 564 U.S. at 609. The Court extended the *Mensing* holding in *Bartlett*, finding that "state-law design-defect claims that turn on the adequacy of a drug's warning" were preempted. *Bartlett*, 133 S.Ct. at 2470. It made this determination by examining what exactly the tort law of New Hampshire, the state at issue, would have required of the generic manufacturer; if federal law prohibits "the remedial action required to avoid liability" under state law, the claim is preempted. *Id.* at 2475–78. The Court noted that changing the chemical makeup of a drug to make it safer, or changing the labeling of the drug, were not viable options for a generic manufacturer under the FDCA, *id.* at 2474–76; the Court also rejected the respondent's argument that the generic manufacturer should have pulled the drug from the market to resolve safety issues that could not be addressed through redesigning the drug or from strengthened labeling. *Id.* at 2474–2478. These decisions did not address the possible liabilities of brand-name manufacturers, which the

Supreme Court had held could be liable when a plaintiff ingests and is harmed by the brand-name drug. *See Wyeth v. Levine*, 555 U.S. 555 (2009). [4]

***4** The Seventh Circuit has already noted that the *Mensing* decision "makes it difficult if not impossible to hold the generic manufacturer liable" for claims of injury caused by a drug's inadequate labeling. *In re Glaxosmith Kline*, No. 14-2051, 557 Fed.Appx. 578 (7th Cir. Jun. 4, 2014) (non-precedential ruling on writ of mandamus in *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 711 (N.D. Ill. 2014)). In particular, the Circuit has adopted *Mensing*'s holding that "the FDCA preempts any state law that requires companies to improve generic drug labels." *Wagner v. Teva Pharm. USA, Inc.*, 840 F.3d 355, 358 (7th Cir. 2016). Though Garner spills much ink to convince the Court otherwise, her negligence (Count VI), negligent misrepresentation (Count VII), and product liability design-defect (Count X), fraud (VIII), and fraudulent concealment (IX) claims fall squarely into the category of cases the Supreme Court has identified as preempted. Plaintiff alleges in each count that Zydus withheld information, failed to propose stronger labels, failed to issue warnings, and failed to warn about the risks. Count I–Count V, Compl. To avoid liability for any of these claims, Zydus would have had to make unilateral changes to its labels or the drug's design—changes that would have been forbidden by FDA regulations.

1. Negligence

In the State of Illinois, a plaintiff making a negligence claim "must allege facts that establish the existence of a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach." *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1096 (Ill. 2012). A duty to warn exists when "there is unequal knowledge, actual or constructive [of a dangerous condition], and the defendant[,] possessed of such knowledge, knows or should know that harm might or could occur if no warning is given." *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1123 (Ill. 2002) (quoting *Schellenberg v. Winnetka Park Dist.*, 596 N.E.2d 93, 97 (Ill. App. Ct. 1992)). Garner's negligence claim is rooted in allegations that "Zydus had a duty to exercise reasonable care in the sale and/or distribution of levofloxacin along with its label, warnings, and advertisements into the stream of commerce[,]" also alleging that Zydus' continued distribution of the drug and its failure to warn patients was negligent when it knew or should have known that the drug was unreasonably dangerous. Count VI, Compl. ¶¶ 74–81. Garner alleges a failure to warn claim precisely within the purview of preemption in *Mensing*, and any claim regarding the design of the labeling, *see* Compl. 25–26, is also destined to fail due to the FDCA requirements and the *Mensing*/*Bartlett* framework.

2. Negligent Misrepresentation

Similarly, Garner's negligent misrepresentation claim relies on allegations that Zydus provided inadequate and untruthful information about the drug. The elements of the claim are:

> (1) a false statement of material fact; (2) carelessness or negligence in ascertaining the truth of the statement by the party making it; (3) an intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statement; (5) damage to the other party resulting from such reliance; and (6) a duty on the party making the statement to communicate accurate information.

First Midwest Bank, N.A. v. Stewart Title Guar. Co., 843 N.E.2d 327, 334–35 (Ill. 2006). Here, Plaintiff alleges the information provided was false, which implies that different information should have been provided.

The regulations require a generic drug's labeling to match the brand name drug's label. 21 U.S.C. § 355(j)(2)(A)(v). Labeling is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or

(2) accompanying such article." 21 U.S.C. § 321(m). The Supreme Court has held "that the phrase 'accompanying such article' is not restricted to labels that are on or in the article on package that is transported," *Kordel v. United States*, 335 U.S. 345, 349 (1948), and deferred to the FDA's interpretation that "Dear Doctor" letters qualify as "labeling," *Mensing*, 564 U.S. at 615 (explaining why "Dear Doctor" letters explicating new risks are not a solution, because generic manufacturers are barred by the FDCA from making representations that stray from the brand name labeling or imply that the generic is therapeutically different). Garner also alleges that Zydus could have done more extensive testing on the product, *id.* at ¶¶ 92–95: even if it had conducted such tests, again, the result would have been that it could not unilaterally change its safety labeling.

***5** Further, Garner's reliance on the Food and Drug Administration Amendments Act of 2007 ("FDAAA") does not avail her: the Seventh Circuit has already noted that while the FDAAA may have allowed more space for generic manufacturers to report and recommend safety issues and negotiate changes to safety labeling for postmarket drugs, *see* in relevant part 21 U.S.C. § 355(o)(4), it did not change the fact that generic manufacturers may not act to change their labels without prior FDA approval. *Wagner*, 840 F.3d at 358–59; *Houston v. United States*, No. 15-2411, 638 Fed.Appx. 508, 513–14 (7th Cir. Feb. 3, 2016) (finding that despite amendments of FDAAA, federal law "still forbid[s] a generic-drug maker from violating the duty of sameness without FDA permission").

3. Fraud

Garner attempts to allege fraud (Count VIII) and fraudulent concealment (Count IX) claims based on the "representations, through national advertising, promotional campaigns, [and] related materials," Count VIII, Compl. ¶ 80, distributed to physicians. Common law fraud is closely tied to negligent misrepresentation, except that the defendant must have had knowledge that his statement was false. *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 591 (1996). As is the case generally with fraud claims, the plaintiff must allege "with specificity and particularity facts from which fraud is the necessary or probable inference, including what misrepresentations were made, when they were made, who made the misrepresentations, and to whom they were made." *Id.; see* Fed. R. Civ. P. 9(b). The related tort of fraudulent concealment requires allegations that the "defendant concealed a material fact when he was under a duty to disclose that fact to plaintiff." *Id.* at 593. For the reasons already discussed, federal law limited the type of information Zydus could distribute. Garner's allegations reciting the elements of the claim without providing the specificity required are insufficient. In any case, Garner fails to allege facts in her complaint regarding any such advertising campaign undertaken by Zydus, or any intent to mislead.

4. Strict Liability

"The theory of strict liability is that one who sells a defective product unreasonably dangerous to the user is liable for the resulting injury." *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 328 (Ill. 1990). "[A] physical defect in the product itself, a defect in the product's design, or a failure of the manufacturer to warn of the danger or to instruct on the proper use of the product" may render it unreasonably dangerous. *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 335 (Ill. 2008), opinion modified on denial of reh'g (Dec. 18, 2008). Garner argues that her strict liability claim succeeds either because levofloxacin was sold with "insufficient warning" about its unreasonable danger, or because it was marketed to treat simple infections despite a risk-utility analysis that would militate against it, and was therefore defective in design. Pl.'s Resp. Zydus Mot. Dismiss 10–11, ECF No. 19. Both of these claims fundamentally would require either a change in labeling or a change in the chemical makeup of the drug, which Zydus could not do, or a "stop-selling" approach, which the Supreme Court has declared unreasonable. *Bartlett*, 133 S.Ct. at 2477–78; *see also Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1140–41 (8th Cir. 2014) (examining that the theory of design defect product liability, whether based in a consumer expectation test of unreasonable dangerousness, or a risk-utility test, is immaterial to the preemption analysis).

5. Warranties

Garner's other claims against Zydus—breach of express warranty (Count XI) and breach of implied warranty of merchantability (Count XII)—face a similar fate. "In a breach of express warranty action under the [Illinois UCC], plaintiff must show a breach of an affirmation of fact or promise that was made a part of the basis of the bargain." *Oggi Trattoria & Caffe, Ltd. v. Isuzu Motors Am., Inc.*, 865 N.E.2d 334, 340 (Ill. App. Ct. 2007) (quoting *Hasek v. DaimlerChrysler Corp.*, 745 N.E.2d 627, 634 (Ill. App. Ct. 2001)).

> ***6** [T]he burden of proof is on the plaintiff to show by a preponderance of the evidence the terms of the warranty, the failure of some warranted part, a demand upon the defendant to perform under the terms of the warranty, a failure of the defendant to do so, a compliance with the terms of the warranty by the plaintiff, and damages measured by the terms of the warranty.

Oggi, 865 N.E.2d at 340 (quoting Hasek, 745 N.E.2d at 638). A breach of implied warranty of merchantability requires that a plaintiff plead: "(1) a sale of goods, (2) that the seller of the goods is a merchant with respect to those goods, and (3) that the goods were not of merchantable quality." *Smith v. Boehringer Ingelheim Pharm., Inc.*, 886 F. Supp. 2d 911, 929 (S.D. Ill. 2012) (quoting *Maldonado v. Creative Woodworking Concepts, Inc.*, 796 N.E.2d 662, 666 (Ill. App. Ct. 2003)). Whether a product is "of merchantable quality" turns on whether it is fit "for the ordinary purposes for which [it is] used." *Id.*

Garner does not explicitly blame the labeling when alleging these claims; however, reviewing Zydus' express warranties and determining whether levofloxacin is fit for its ordinary purpose (treatment of common bronchitis, urinary tract infection and other non-life threatening bacterial infections) and the risk of injury therein, requires a review *of the safety labeling*. Therefore, Garner's warranty claims sound in a failure to warn theory of liability. *See* Compl. 35–37, 58; Count XI, Compl. ¶ 73–75; Count XII, Compl. ¶ 79. "Although *Mensing* and *Bartlett* dealt with failure to warn and design defect claims, respectively, federal courts have extended their rationale to similar state law claims" when those claims rely on "the generic manufacturer's failure to provide adequate information" and are therefore preempted. *Wagner*, 840 F.3d at 358 (quoting *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476 (5th Cir. 2014)); *Houston*, No. 15-2411, 638 Fed.Appx. at 513–14 (affirming dismissal of the defective design, negligence, consumer fraud, battery, and breach of express and implied warranty claims of plaintiff injured by generic drug). *See also Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139–40 (8th Cir. 2014) (incorporating the *Mensing* holding, and finding that the FDCA preempted the plaintiff's breach of implied warranty claim because the generic manufacturer "could only avoid liability under Missouri law by redesigning its product, changing its labeling, or leaving the market"); *In re Darvocet*, 756 F.3d at 934–35 (discussing how the combination of the duty of sameness in labeling with the rejection of the "stop selling" argument insulates generic manufacturers from breach of express or implied warranty claims).

For the above reasons, all of Garner's claims against Zydus fail as a matter of law and must be dismissed.

C. Claims Against Janssen

Garner brings five claims against Janssen: (I) negligence, (II) negligent misrepresentation, (III) fraud, (IV) fraudulent concealment, and (V) product liability negligence. Janssen argues that because it did not manufacture, distribute, or sell the generic form of levofloxacin taken by Garner that it owed her no duty of care. Janssen Mem. Supp. Mot. Dismiss 7, ECF No. 10.

1. Negligence

Garner alleges that "Janssen was negligent in Levofloxacin's design and warnings[.]" Pl.'s Resp. Janssen's Mot. Dismiss 6–13. She further argues that the labeling sameness requirement made it clearly foreseeable that any mistake in a brand name drug's label would be repeated in the labeling of the generic drug, imposing a duty of care upon Janssen. *Id.* at 12. Janssen recommends that the Court follow *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), a Fourth Circuit case holding that brand name manufacturers may not be held liable (in that case, under a theory of negligent misrepresentation) for injuries caused by the product of another manufacturer. *Foster*, 29 F.3d at 170–71. *Foster* held that "impos[ing] a duty [on brand name manufacturers] would be to stretch the concept of foreseeability too far." *Id.* at 171. Most courts faced with so called "innovator liability" have followed *Foster*, but the Seventh Circuit has not yet weighed in. *See e.g. Houston*, 638 Fed.Appx. at 513–14 (noting that the Seventh Circuit "has not addressed whether a consumer of a generic drug may sue the brand-name manufacturer" but avoiding the issue due to an expired statute of limitations). Therefore, the Court examines Illinois tort principles to determine the extent to which Janssen may be held liable under law.

***7** To reiterate, a plaintiff attempting to state a claim for common law negligence "must allege facts that establish the existence of a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach." *Simpkins*, 965 N.E.2d at 1096. In Illinois, while the law does not generally impose an affirmative duty to protect strangers, the existence of a duty of care "does not depend upon contract, privity of interest or the proximity of relationship, but extends to remote and unknown persons." *Simpkins*, 965 N.E.2d at 1097 (quoting *Widlowski v. Durkee Foods, Div. of SCM Corp.*, 562 N.E.2d 967, 968 (Ill. 1990)). Under Illinois law, the analysis of whether a duty of care exists in a relationship is "nebulous" but guided by four factors: (1) the reasonable foreseeability of the injury, (2) the likelihood of the injury, (3) the magnitude of the burden of guarding against the injury, and (4) the consequences of placing that burden on the defendant. *Simpkins*, 965 N.E.2d at 1097.

In the well-regulated pharmaceutical industry, Janssen, a brand-name manufacturer, is surely not blindsided to find out that the equivalent of its Levaquin labels was imposed on generic versions of levofloxacin and that doctors and patients would rely on the labeling composed by Janssen even when using the generic drug. *See Dolin v. SmithKline Beecham Corp.*, 62 F.Supp.3d at 711. Further, it is a common practice, and therefore foreseeable, for a doctor to prescribe a name brand drug and the pharmacy to fill it with the generic version. The likelihood that Janssen's alleged design or labeling negligence would cause injury is high. Janssen still shoulders the responsibility of updating Levaquin's safety labels so the burden of guarding against injury is marginally low. *See Dolin*, 62 F. Supp. 3d at 715 (noting that the brand-name defendant "will not be tasked with the burden of crafting one new warning label for [its own drug], and then other discrete warnings for various generic iterations of the drug—that all of the iterations of [the drug] are bio-equivalent and require the same warning is precisely the point.").

Other courts have expressed trepidation about the consequences of holding brand-name manufacturers liable for injury caused by generics. *See e.g. In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014) (citing "grave health policy consequences associated with recognizing brand manufacturer liability in these situations[,] including higher priced brand name drugs and fewer innovative drugs."). Finding a duty of care in this scenario does not signal the Court's intent to hold brand-name manufacturers liable for the manufacturing errors of an entire industry—to make it an "insurer[ ]" of the industry, as Janssen suggests. Janssen's Reply 10. This decision simply allows Garner to attempt to recover for deficiencies in levofloxacin's label from the one entity, under federal law, that has unilateral ability to strengthen the label. In considering the factors important in determining the existence of a duty relationship, the Court finds that a sufficient relationship exists between Janssen and Garner who ingested the generic equivalent of Levaquin for the law to impose a duty of care upon Janssen to adequately warn of the risks of levofloxacin. Garner alleges Janssen breached that duty when it failed to strengthen the warning labels.

The next step in the negligence analysis is identifying causation: liability for negligence may not be "imposed based merely on a breach of duty, without causation being established." *Lewis v. Lead Indus. Ass'n, Inc.*, 793 N.E.2d 869, 874 (Ill. App. Ct.

2003). Garner alleges Janssen created levofloxacin's safety labeling, that it failed to warn of certain side effects, and that if she had known of those side effects she would have not taken levofloxacin. The Court agrees: an extra link in the causal chain (here, the transfer of the identical label from the branded drug to the generic drug) does not break it. It is possible for a plaintiff to show that injuries caused by mislabeling on a generic medication can be directly traced back to the brand name manufacturer's creation of the label. *See Pecher v. Owens-Illinois, Inc.*, 859 F.3d 396, 401 (7th Cir. 2017) (citing favorably *Dolin*, 62 F. Supp. 3d at 711, and opining that "the branded manufacturer can be said to have 'caused' any mislabeling by a generic drug manufacturer, even if the branded drug manufacturer had no hand in the manufacture or distribution of the drug or the labels."). Much of the case law refusing to hold a manufacturer liable for another manufacturer's product occur in cases when it is unclear which manufacturer, in a sea of manufacturers working in an industry, has created the faulty product. *See Lewis*, 793 N.E.2d. at 875. As the *Dolin* court noted, that is not the question here. Instead, the Court is deciding whether to hold a brand name company "liable for tortious conduct that was extrinsic to the manufacturing process and that contributed to Plaintiff's injury." *Dolin*, 62 F. Supp. 3d at 718. Garner has adequately alleged causation.

2. Negligent Misrepresentation

***8** Garner next asserts a claim for negligent misrepresentation against Janssen. This claim requires:

> (1) a false statement of material fact; (2) carelessness or negligence in ascertaining the truth of the statement by the party making it; (3) an intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statement; (5) damage to the other party resulting from such reliance; and (6) a duty on the party making the statement to communicate accurate information.

First Midwest Bank, N.A., 843 N.E.2d at 334–35. Janssen's duty to communicate accurate information about levofloxacin exists for the same reasons discussed above in connection to the common law negligence claim. Garner has alleged that Janssen's label may not have contained a sufficiently strong warning regarding the use of levofloxacin for the treatment of simple infections. Garner alleges that Janssen promoted levofloxacin to physicians as safe and effective for treatment of conditions like a urinary tract infection, without taking reasonable care—for instance, via testing—to ensure that the drug was, in fact, safe for those purposes. Janssen, according to Garner, intended that representations regarding the drug's safety and recommended use, made on its safety labeling and in its marketing materials, would lead doctors to prescribe the drug to patients, who could suffer its adverse effects. Janssen has successfully alleged a claim against Janssen for negligent misrepresentation.

3. Product Liability

The product liability negligence claim requires largely the same allegations as the other negligence claims, and for that reason it survives. Product liability negligence claims are rare, but they utilize the framework of a common law negligence claim (requiring a duty of care, breach of that duty, and proximate causation of injury due to the breach), taking into account that "[a] manufacturer has a non-delegable duty to design reasonably safe products." *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 270 (Ill. 2007). Admittedly, because Janssen did not physically manufacture the pill taken by Garner, the claim presents some analytical complexities. However, a plaintiff may plead a product liability negligence claim by pointing to a way in which "the product was unreasonably dangerous and defendant failed to warn of its dangerous propensity." *Blue v. Envtl. Eng'g, Inc.*, 828 N.E.2d 1128, 1141 (Ill. 2005). The fundamental crux of Garner's claim is that levofloxacin was not properly labeled for the purpose for which it was marketed, and Janssen is the undisputed creator of those labels. Compl. 22–23. Garner pleads her negligence claim sufficiently, and the closely related product liability negligence claim stands as well. *Blue*, 828 N.E.2d at 1141 (clarifying that "a design defect suit [as opposed to a suit based on a manufacturing defect] is more akin to a negligence claim."). Lastly, Garner has raised claims of fraud and fraudulent concealment. She alleges that Janssen intentionally disseminated false,

misleading material in advertising and promotional campaigns and that it did not timely disclose risks associated with the use of levofloxacin. *See* Compl. 20–22. A plaintiff must allege, "with specificity and particularity, facts from which fraud is the necessary or probable inference, including what misrepresentations were made, when they were made, who made the misrepresentations, and to whom they were made." *Connick v. Suzuki Motor Co.*, 675 N.E.2d at 591. Garner does not do this. She argues that inferences of fraud can be made from the presumption that "Janssen would want doctors to prescribe Levaquin, or its generics" and so would be driven to make misrepresentations on the labeling, or perhaps that Janssen wanted to avoid liability by continuing to advertise levofloxacin as "safe and effective" rather than making changes to the labeling. Resp. Janssen Mot. Dismiss 15–16. These allegations are speculative and do not raise a probable inference of fraudulent conduct. The fraud and fraudulent concealment claims against Janssen (Counts III and IV) are dismissed.

CONCLUSION

***9** For the foregoing reasons, Zydus' Amended Motion to Dismiss, ECF No. 17, is GRANTED as to the counts against Zydus (Counts VI-XIII). Janssen's Motion to Dismiss, ECF No. 10, is GRANTED IN PART, as to Counts III and IV. Garner's claims against Janssen for common law negligence, negligent misrepresentation, and product liability negligence (Counts I, II, and V) may proceed. Janssen's Motion for Leave to File a Reply, ECF No. 23, is GRANTED.

All Citations

Not Reported in Fed. Supp., 2017 WL 6945335

Footnotes

1 For the purpose of resolving a motion to dismiss, the factual allegations in a plaintiff's complaint are assumed to be true. *McCauley v. City of Chicago*, 671 F.3d 611, 616 (7th Cir. 2011). Therefore, unless otherwise noted, the facts set forth here are drawn from Garner's Amended Complaint, ECF No. 3.

2 Neuropathy, according to the National Institute of Health, means "nerve disease or damage"; peripheral neuropathy refers to damage in the peripheral nervous system that connects to and sends information to the brain and spinal cord. NAT'L INST. OF NEUROLOGICAL DISORDERS AND STROKE, NAT'L INST. OF HEALTH, "Peripheral Neuropathy Fact Sheet" (Dec. 2014) https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Peripheral-Neuropathy-Fact-Sheet

3 Garner alleges that Ortho-McNeil is a wholly owned subsidiary of Johnson & Johnson and that it, in concert with the other defendants, created the Levaquin warning label.

4 In *Wyeth*, the Supreme Court held that a federal regulation, known as the "changes being effected" ("CBE") regulation, permitted brand name manufacturers to unilaterally strengthen its warning label before it was approved by the FDA and rejected the brand name manufacturer's argument that federal regulations made complying with state law duties impossible. *Wyeth*, 555 U.S. at 571 (citing 21 C.F.R. §§ 314.70(c)(6)(iii)(A),(C)).

2014 WL 10937406 (Mass.Super.) (Trial Order)
Superior Court of Massachusetts.
Middlesex County

Mary CARDINAL,
v.
ELSEVIER INC., & others and eight companion cases.*

No. MICV201104442.
August 11, 2014.

Memorandum of Decision and Order on Brand-Name Defendants' Motions for Summary Judgment

Bruce R. Henry, Judge.

***1** * Gold Standard, Inc.; Alaven Pharmaceuticals; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceuticals Industries, Ltd.; Schwarz Pharma, Inc.; Wal-Mart Stores, Inc., Corp.; Wyeth, Inc.; Wyeth Pharmaceuticals, Inc.; Wolters Kluwer Health; Wolters Kluwer US

* White v. Elsevier Inc., & others, MICV2011-04441; Bishop v. Elsevier Inc., & others, MICV2011-04443; Wyan v. Elsevier Inc., & others, MICV2011-04444; Scott v. Elsevier Inc., & others, MICV2011-04445; Purcell, & another v. Barr Pharmaceuticals, LLC, & others, MICV2011-04446; Martin v. Elsevier Inc., & others, MICV2011-04447; Felker v. Elsevier Inc., & others, MICV2011-04448; Daley, & another v. Elsevier Inc., & others, MICV2011-04449.

Contending that long-term use of metoclopramide ("MCP"), the generic bioequivalent of the brand-name drug Reglan (collectively, "Reglan/MCP"), has caused them severe and permanent neurological injuries, the plaintiffs in these nine cases have asserted claims against brand-name manufacturers of Reglan/MCP; against generic manufacturers of Reglan/MCP; against the parties who produce the Patient Education Monographs concerning Reglan/MCP; and against the pharmacies that dispense Reglan/MCP. Defendants Alaven Pharmaceuticals, Schwarz Pharma, Inc., Wyeth LLC, and Wyeth Pharmaceuticals, Inc. (collectively, "Brand-Name Defendants") have filed a joint motion for summary judgment in this case, arguing that, as a matter of the applicable Oklahoma law, the plaintiff cannot hold them liable for the injuries she allegedly sustained from having ingested the generic bioequivalent of Reglan/MCP. For the following reasons, the Brand-Name Defendants' motion for summary judgment is ***ALLOWED***.

DISCUSSION

At all times relevant to this litigation, the plaintiff, Mary Cardinal ("Cardinal") was an Oklahoma resident. She never received any medical treatment in Massachusetts, was never prescribed Reglan/MCP in Massachusetts, and never filled her Reglan/MCP prescriptions in Massachusetts. During the relevant time period, Cardinal ingested generic Reglan/MCP, manufactured by defendant Teva Pharmaceuticals Industries, Ltd., and its subsidiary Teva Pharmaceuticals USA, Inc. She alleges that the long-term ingestion of these generic tablets allegedly caused her to develop tardive dyskinesia, akathesias in her entire body, and orofacial dyskinesias, all of which are movement disorders. Cardinal ceased taking Reglan/MCP in June 2009. Cardinal has alleged four claims against the Brand-Name Defendants: Negligence, Negligent Misrepresentation, and Negligent Supply of Information (Count I); Misrepresentation and Fraud (Count IV); Joint and Several Liability (Count VII); and Violation of G.L. c. 93A (Count IX).

Asserting that Oklahoma law applies, the Brand-Name Defendants seek summary judgment on Cardinal's claims against them because it is undisputed that she did not ingest brand-name Reglan/MCP manufactured or sold by the Brand-Name Defendants and therefore, as a matter of law, the Brand-Name Defendants owed Cardinal no duty. Cardinal does not dispute that Oklahoma law applies. Instead, she argues that Oklahoma courts have not addressed the precise issue here, and that, regardless of whether the court characterizes the "product" as the pill Cardinal actually ingested or as the design, research and development, marketing, post-market surveillance, and warning label of Reglan/MCP, the Brand-Name Defendants are still subject to liability for Cardinal's alleged injuries. Further, she asserts that she seeks to hold the Brand-Name Defendants liable under a negligence theory as well as under a strict liability theory.

***2** In Oklahoma, "[a] plaintiff injured by a defective product can utilize various theories to recover for injuries caused by the product." *Honeywell v. GADA Builders, Inc.*, 271 P.3d 88, 96 (Okla. Civ. App. 2012). Therefore, "a plaintiff is not required to elect one theory of liability" but, as Cardinal has done, may assert theories of both negligence and strict products liability. *Id.* Accordingly, regardless of the theories under which Cardinal proceeds, her case is still a product liability action as it "is based on an injury caused by a defective product." *Id.*

"To maintain a products liability action, a plaintiff must prove: (1) the product was the cause of the injury; (2) the defect existed in the product at the time it left the manufacturer's possession and control … ; and (3) the defect made the article 'unreasonably dangerous' to plaintiff or his property ...." *Prince v. B.F. Ascher Co., Inc.*, 90 P.3d 1020, 1026 (Okla. Civ. App. 2004), citing *Kirkland v. General Motors Corp.*, 521 P.2d 1353, 1362-1363 (Okla. 1974). It is undisputed that Cardinal only ingested generic Reglan/MCP, and the Brand-Name Defendants argue they are entitled to summary judgment as they did not manufacture the generic Reglan/MCP that allegedly caused Cardinal's injuries. The parties agree that there is no Oklahoma case on point. The Tenth Circuit, however, applying Oklahoma law, "predict[ed] - consistent with the trend among courts nationally and Oklahoma tort law in general - that [Oklahoma courts] would not recognize a duty flowing from brand-name drug manufacturers to consumers of generic drugs." *Schrock v. Wyeth*, 727 F.3d 1273, 1281-1282 (10th Cir. 2013); see id at 1285 (listing "three principal rationales" on which courts in other jurisdictions relied to reach their conclusions that "brand-name manufacturers are not liable to consumers of generic drugs"). This court finds the Tenth Circuit's decision persuasive. See *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, - F.3d -, 2014 WL 2959271, *30 (6th Cir. June 27, 2014) (accepting Tenth Circuit's interpretation of Oklahoma law and concluding that brand manufacturers did not owe generic consumers "duty that could give rise to liability under Oklahoma law").

In strict products liability actions, "Oklahoma courts usually require that a defendant have some relationship with the product *alleged to have caused a plaintiff's injuries*, either through manufacturing, selling, or distributing the product." *Schrock*, 727 F.3d at 1282 (emphasis added). Similarly, in negligence actions, "Oklahoma courts have also required a relationship between the defendant company and the product *at issue* ...." *Id.* (emphasis added). Consequently, where the plaintiffs claimed that their injuries arose from the ingestion of generic Reglan/MCP, the Tenth Circuit held that "[t]he brand-name manufacturers do not have any relationship with the [plaintiffs]." *Id*.

Cardinal argues that the actual "product" that allegedly caused her injuries, however, is the Reglan/MCP label that represented that Reglan/MCP caused minimal side effects and failed to warn that it frequently caused central nervous system side effects and extrapyramidal symptoms. Cardinal's argument is inconsistent with Oklahoma products liability law. Specifically, "[a]n alleged defect in a product may be the result of a problem in a product's design or manufacture or it may be the result of *inadequate warnings regarding use of the product.*" *Attocknie v. Carpenter Mfg., Inc.*, 901 P.2d 221, 227 (Okla. Civ. App. 1995) (emphasis added) (citation omitted). With respect to an inadequate warnings claim, "[t]he manufacturer of a product has a duty to warn the consumer of potential dangers which may occur *from the use of the product* when it is known or should be known that hazards exist." *McKee v. Moore*, 648 P.2d 21, 26 (Okla. 1982) (emphasis added). It follows, then, that the inadequate warnings, i.e., the label itself, is not the product, but a way in which a plaintiff can claim that the product is defective. See *McKee,* 648 P.2d at 26; *Attocknie*, 901 P.2d at 227; cf. 21 C.F.R. § 201.1 (providing that "[a] drug or drug product … in finished package form is misbranded … if its label" does not contain certain information).

***3** *Schrock* is also instructive on this point as well. See 727 F.3d at 1283. Although, as Cardinal points out, the Tenth Circuit did not address this issue as Cardinal has phrased it, it considered the brand-name manufacturers' duty to warn under similar circumstances. See *id.* First, the court rejected the plaintiffs' argument "that Oklahoma law imposes a duty upon brand-name manufacturers to speak rather than to remain silent in certain circumstances" because "the brand-name manufacturers had no relationship with the" plaintiffs. Id. The court also rejected the plaintiffs' argument "that under Oklahoma law, liability may be imposed if a defendant has knowledge of a dangerous situation yet fails to warn of that danger[,]" holding that the two cases on which the plaintiffs relied did not persuade the court "that Oklahoma courts would impose a duty on drug manufacturers to warn of dangers in their competitors' products." *Id.*

Accordingly, the "product" at issue in this case is the generic Reglan/MCP that Cardinal ingested and that allegedly caused her injuries. As the Brand-Name Defendants did not manufacture the generic Reglan/MCP that Cardinal ingested, they have no relationship with the product or, as a consequence, with Cardinal herself.

ORDER

For the foregoing reasons, the Brand-Name Defendants' motion for summary judgment (paper #35) is ***ALLOWED***.

DATED: August11, 2014

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Bruce R. Henry

Associate Justice

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2013 WL 5691993 (N.Y.Sup.), 2013 N.Y. Slip Op. 32563(U) (Trial Order)
Supreme Court, New York.
Part 32
New York County

Torrie WEESE, individually and as Natural Parent and Guardian of Misty Jo Weese, a Minor, Plaintiffs,
v.
PFIZER, INC., Defendant.

No. 153742/12.
October 8, 2013.

Trial Order

Carol E Huff, Judge.

***1** CAROLE. HUFF, J.:

In this product liability action, plaintiffs move, pursuant to CPLR 3211(b), to dismiss the twenty-eighth affirmative defense of defendant Pfizer, Inc., which states: "Pfizer specifically denies all allegations of duty, breach, negligence, defect, causation, and all forms of damages and demands strict proof thereof." Pfizer cross moves to dismiss the complaint.

Plaintiff Torrie Weese, during her pregnancy, was prescribed and took sertraline, a generic form of the anti-depressant Zoloft. Plaintiffs allege that the sertraline caused plaintiff Misty Jo Weese to be born with serious heart defects. Zoloft is manufactured by Pfizer; sertraline is not. Plaintiff contends that because federal law requires the generic medication to display the same warning label as the original medication, Pfizer owed a duty to plaintiffs that it breached by issuing an allegedly inadequate warning label with its original product.

A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. *See*, *e.g.*, 21 U.S.C. §§ 355(b)(1), (d); *Wyeth v Levine*. 555 U.S. 555, at 570-571 (2009). A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's. *See*, *e.g.*, 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7).

Pliva. Inc. v Mensing, 131 S Ct 2567, 2574 (2011).

The issue presented - whether a drug manufacturer that did not manufacture the product alleged to have caused injury owes a duty to a plaintiff because of the required identity of warning labels - has not been addressed by New York State courts.

[A] duty of reasonable care owed by the tort-feasor to the plaintiff is elemental to any recovery in negligence. Foreseeability of injury does not determine the existence of duty. Unlike foreseeability and causation, both generally factual issues to be resolved on a casc-by-case basis by the fact finder, the duty owed by one member of society to another is a legal issue for the courts.

Eiseman v State of New York, 70 NY2d 175, 187 (1987) (citations omitted).

In seeking to establish a duty in this context, plaintiff cites examples of purportedly analogous cases, including most notably *Palka v Servicemaster Mgt. Corp.*. 83 NY2d 579 (1994); *Sage v Fairchild-Swearingen Corp*., 70 NY2d 579 (1987); and *Weigand v Univ. Hosp. of New York Univ. Med. Ctr*.. 172 Misc2d 716 (Sup Ct NY County 1997).

***2** In *Palka*, the plaintiff nurse was injured when a mounted wall fan fell on her while she worked in a hospital. She sued the defendant company that had contracted with the hospital to manage, among other things, the maintenance department. In *Sage*, the plaintiff injured her finger while working in an aircraft manufactured by the defendant. Her finger got caught on a hook attached to the doorway of the cargo compartment. Sometime prior to the accident, the hook had been replaced with a copy made by an employee of the airline, which was not related to the defendant manufacturer. In *Weigand*, the plaintiff underwent a blood transfusion during surgery and received blood contaminated with HIV. He sued, among others, the blood banking industry's national trade association, contending that it negligently established inadequate blood collection standards. The courts in each of these cases found that defendants had had a duty with respect to the plaintiffs.

In each of these cases, as in the instant case, there was no direct connection between the defendants, the object that caused harm, and the plaintiff. However, unlike here, in each case the defendant intentionally took actions that affected the specific outcome. In *Palka*, the defendant took on the responsibility of ensuring a safe work environment when it contracted with the hospital to manage the maintenance department. In *Sage*, the defendant manufactured and sold the entire aircraft, and only a minor part was replaced with an identical part. In *Weigand*, the defendant undertook the role of regulating the quality of blood to be transfused. The volitional actions of each of these defendants was key in imposing a duty on them.

In the product liability context, the *Sage* court stated that imposition of strict liability is justified when a seller, "by marketing his product, has *undertaken* a special responsibility toward members of the consuming public who may be injured by it. The public has a right to expect that sellers will stand behind *their* goods. Thus, the burden of accidental injuries caused by products *intended* for consumption has been placed upon those who market them. ..." *Sage*, *supra*, at 585 (emphasis added).

In this case, Pfizer had no intentional role in placing the specific product with the plaintiff. It was not the seller. Indeed, a third party - a competitor - manufactured and sold the product. The connection defendant seeks to establish through the warning label is even more attenuated. The label existed as a requirement of another third party, the federal government, aimed at the generic manufacturer. It is to be expected that Pfizer has a duty in connection with its own products and labels. However, that duty should not extend to products and labeling over which it has no control, even if those products and labels mirror its own, because it has done nothing toward putting them in the hands of consumers.

***3** Plaintiff has failed to demonstrate that precedent exists to extend a duty to defendant in this context. Accordingly, it is

ORDERED that plaintiffs' motion to dismiss defendant's twenty-eighth affirmative defense is denied; and it is further

ORDERED that defendant's cross motion to dismiss the complaint is granted.

Dated OCT O8 2013.

<<signature>>

CAROL E. HUFF

J.S.C.

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2009 WL 4924722 (Fla.Cir.Ct.) (Trial Order)
Circuit Court of Florida,
Fifteenth Judicial Circuit.
Palm Beach County

Gayle DIETRICH and William H. Dietrich, Plaintiffs,
v.
WYETH, INC. d/b/a Wyeth, Individually and as Successor-In-Interest to A.H. Robbins Company, Inc. and American Home Products Corporation; ESI Lederle, Inc.; Schwarz Pharma, Inc.; Wyeth Pharmaceuticals, Inc.; Mckesson Corporation; Purepac Pharmaceutical Co.; Alpharma Uspd, f/k/a Barre-National, Inc.; Alpharma, Inc.; Actavis, Inc.; Actavis MID Atlantic, LLC; Actavis Elizabeth, LLC; Barre Parent Corporation; Pliva, Inc., f/k/a/sidmak Laboratories, Inc.; Barr Pharmaceuticals, Inc.; Craig G. Sultan, D.O., and Craig G. Sultan, D.O., P.A., Defendants.

No. 50-2009-CA-021586 XXX MB.
December 21, 2009.

Order Granting Motion for Summary Judgment of Defendants Wyeth, Wyeth Pharmaceuticals Inc., and Schwarz Pharma, Inc., and Final Summary Judgment for Defendants Wyeth, Wyeth Pharmaceuticals Inc., and Schwarz Pharma, Inc.

Robin Rosenberg, Circuit Judge.

THIS CAUSE came before the Court on the August 31, 2009 motion of Defendants Wyeth, Wyeth Pharmaceuticals Inc. (collectively, "Wyeth"), and Schwarz Pharma, Inc. ("Schwarz") (collectively, "Defendants"), for summary judgment on Counts I-V of Plaintiffs' Complaint to the extent that those counts relate to them. [1] The parties submitted written memoranda in support and in opposition to this motion, and a hearing was held on December 4, 2009. The Court having reviewed the record, including the submissions of the parties, having heard argument of counsel and being otherwise fully advised in the premises, finds as follows:

The factual background of this case overall and the involvement of Wyeth and Schwarz are undisputed. This case involves the prescription drug metoclopramide. Plaintiffs allege that Mrs. Dietrich suffered injuries resulting from her use of metoclopramide from approximately 2003 until approximately 2006. Metoclopramide is available in both name brand (Reglan®) and generic formulation. Wyeth manufactured and distributed Reglan® from approximately 1989 through late December 2001. In late December 2001, Schwarz acquired the rights to Reglan® tablets from Wyeth. Schwarz thereafter manufactured and/or distributed Reglan® tablets until 2008. Since the mid-1980s, several companies - including some of the generic manufacturers sued here as defendants - at different times manufactured and distributed generic metoclopramide.

In response to requests for admissions, Plaintiffs admit that Mrs. Dietrich ingested only generic metoclopramide manufactured by companies other than Wyeth and Schwarz. Plaintiffs further admit that Mrs. Dietrich did not ingest any metoclopramide manufactured or distributed by Wyeth or Schwarz. *See id.* Nonetheless, Plaintiffs seek to hold both Wyeth and Schwarz liable for Mrs. Dietrich's alleged injuries in their capacity as name brand manufacturers. Plaintiffs' theory is that, because Wyeth and Schwarz manufactured name brand metoclopramide, both companies can be held liable for allegedly failing to adequately warn about the risks associated with generic metoclopramide. Plaintiffs further contend that both companies are liable because Mrs. Dietrich's physician prescribed generic metoclopramide in reliance on the alleged misrepresentations made by Wyeth and Schwarz about Reglan® and metoclopramide in the Reglan® label and elsewhere. Specifically, Plaintiffs assert the following

causes of action against Wyeth and Schwarz: Negligence (Count I); Strict Liability (Count II); Breach of Warranties (Count III); Misrepresentation and Fraud (Count IV); and Negligence per se (Count V).

All of Plaintiffs' causes of action are barred under Florida law because Plaintiffs admit, and the record establishes, that Mrs. Dietrich ingested only generic metoclopramide and never ingested metoclopramide, whether name brand Reglan® or generic, manufactured by Wyeth or Schwarz. A continuous line of well-established and binding Florida law holds that a product manufacturer cannot be held liable under any theory of liability - be it based in traditional product liability under strict liability or negligence, or fraudulent or negligent misrepresentation, or otherwise - if the plaintiff never used that manufacturer's product. *See Engle v. Liggett Group, Inc.,* 945 So. 2d 1246, 1276 (Fla. 2006); *Conley v. Boyle Drug Co.,* 570 So. 2d 275, 286 (Fla. 1990).

In *Engle,* the Court directed judgment for several defendants that did not manufacture or sell the products that the plaintiffs used. *See* 945 So. 2d at 1276. In doing so, the Court affirmed the reasoning of the intermediate appellate court that "[i]t is aphoristic that a plaintiff cannot prevail on claims for negligence, breach of warranty or strict liability, unless the plaintiff establishes that the product which allegedly caused the plaintiffs injury was manufactured or sold by the defendant." *Id. (citing Liggett Group Inc. v. Engle,* 853 So. 2d 434, 466 n.46 (Fla. 3d DCA 2003), *aff'd on this point, rev'd on other grounds,* 945 So. 2d 1246). Thus, no liability existed because " 'it [was] undisputed that the [] defendants did not manufacture or sell any of the products that allegedly caused injury to the individual plaintiff representatives.' " *Id. (quoting Liggett Group,* 853 So. 2d at 466 n.46). The Court affirmed that holding on all of the plaintiffs' claims, including those based in misrepresentation and fraud, for the simple reason that the plaintiffs never used those defendants' products. *See id.*

In *Conley,* the Court adopted a very limited version of market-share liability under narrow circumstances, but refused to expand Florida tort law to allow liability against a pharmaceutical manufacturer that did not manufacture the drug used by the plaintiff. *See* 570 So. 2d at 286. The Court reasoned that "[w]here a plaintiff can identify a specific tortfeasor as causing her injury and traditional remedies are thus available, we see no reason for resort to a remedy based on the concept of risk contribution." *Id.* As a result, the Court held that "[a]n individual defendant may exculpate itself from liability by proving by a preponderance of the evidence that it did not produce or market the type of [pharmaceutical] taken by the plaintiffs mother ...." *Id.* Therefore, no liability existed under claims of negligence, strict liability, breach of warranty, and fraud. *See id.* at 279, 286.

Engle and *Conley* are only two more recent cases in a long and unbroken line of Florida authority holding that a product manufacturer cannot be liable, regardless of the claim or theory asserted, when the plaintiff did not use or consume that manufacturer's product. *See West v. Caterpillar Tractor Co.,* 336 So. 2d 80, 87 (Fla. 1976) (adopting strict liability when a product user establishes "the manufacturer's relationship to the product in question ... and the existence of the proximate causal connection between such condition and the user's injuries"); *Vecta Contract, Inc. v. Lynch,* 444 So. 2d 1093, 1094 (Fla. 4th DCA 1984) ("In a products liability case it is necessary to present evidence that the defendant manufactured or produced the product that caused the injury."); *see also, e.g., Wallis v. Grumman Corp.,* 515 So. 2d 1276, 1277 (Fla. 1987) ("the duty to warn of a defect arises because of [defendant's] status as a manufacturer or seller of the [product]."); *Mahl v. Dade Pipe & Plumbing Supply Co.,* 546 So. 2d 740, 740-41 (Fla. 3d DCA 1989) (affirming summary judgment when plaintiff "could not identify [defendant] as having produced the [product] involved"); *Felix v. Hoffmann-LaRoche, Inc.,* 513 So. 2d 1319, 1320 (Fla. 3d DCA 1987), *approved,* 540 So. 2d 102 (Fla. 1989) ("a drug manufacturer owes a duty to warn prescribing physicians of the dangerous side effects of its prescription drugs."); *Johns-Manville Sales Corp. v. Janssens,* 463 So. 2d 242, 249 n.4 (Fla. 1st DCA 1984) ("a manufacturer is legally obligated to make statements of warning to users of its products."); *Matthews v. GSP Corp.,* 368 So. 2d 391, 392 (Fla. 1st DCA 1979) (defendant could not be held liable absent evidence that allegedly defective product was manufactured or sold by the defendant). [2]

Another Florida trial court previously disposed of identical theories against Wyeth and Schwarz when the plaintiff used only generic metoclopramide. *See Sharp v. Leichus,* No. 2004-CA-0643, 2006 WL 515532, at *2-*4 (Fla. Cir. Ct. 2d Jud. Cir. Feb. 17, 2006), *aff'd per curiam,* 952 So. 2d 555 (Fla. 1st DCA 2007). [3] In *Sharp,* the court granted summary judgment for Wyeth and Schwarz, holding that "[i]t is well-settled under Florida law that a plaintiff may only recover from the defendant who manufactured or sold the product that caused the injuries in question"). *Id.* at *2. The court further rejected the plaintiffs' "novel

theory of recovery" and held "that a name brand manufacturer was under no duty to the consumers of another company's product and could not be held liable for injuries caused by the ingestion of a competing generic product." *Id.* at *4. The court reasoned that *Conley* barred all of the plaintiffs' claims, whether plaintiffs styled them under negligence, fraud, misrepresentation, or anything else. *See id.* at *6.

When the trial court decided *Sharp,* the underlying opinion in *Engle* was still under review by the Supreme Court of Florida. Nonetheless, the law in Florida at that time was already established under *Conley* and a long line of cases that uniformly applied what can only be deemed a fundamental principle of Florida tort and product-liability law. Today, after the addition of the Court's holding in *Engle,* Florida law is even more settled. Plaintiffs, such as the Plaintiffs here, have no cause of action against a product manufacturer unless they actually used that manufacturer's product.

Against the weight of binding authority, Plaintiffs make several arguments, all of which lack any support in Florida law. Plaintiffs argue that Wyeth and Schwarz owed a duty to Mrs. Dietrich even though she never used their product. As discussed, nothing in Florida law imposes such a duty. The concept of duty under *McCain v. Florida Power Corp.,* 593 So. 2d 500 (Fla. 1992), applies to a product manufacturer to the extent that the manufacturer's own product is involved. "It has nothing to do with imposing a duty on a person or entity for injuries caused by *another* company's property or products." *Sharp,* 2006 WL 515532, at *6 (emphasis in original).

Duty requires more than foreseeability alone. Instead, duty arises when the defendant is in the position to control the alleged risk or creates that risk. *See, e.g., Aircraft Logistics, Inc. v. H.E. Sutton Forwarding Co.,* 1 So. 3d 309, 311 (Fla. 3d DCA 2009) (holding that no duty existed when nothing "demonstrated] that [defendant] was in a position to control the risk, or that its conduct created a broader zone of risk"); *Johnson v. Constr. Mgmt., Inc. v. Lopez,* 902 So. 2d 206, 208-09 (Fla. 3d DCA 2005) (reasoning that "[o]ne important attribute of a legal duty that is assumed in many cases but not expressed is that the defendant must have had the ability to avoid the risk."); *Hernandez v. Tallahassee Med. Ctr.,* 896 So. 2d 839, 841 (Fla. 1st DCA 2005) (duty requires "evidence or allegations showing that ... defendant's conduct created or controlled the risk"); *Aguila v. Hilton, Inc.,* 878 So. 2d 392, 396-97 (Fla. 1st DCA 2004) (holding that no duty existed unless the defendant "had the ability to avoid the risk," was "in a position to control the risk," and "the risk was created by the alleged negligence"). [4] Here, it cannot be said that Wyeth and Schwarz were in a position to control a generic manufacturer's conduct regarding the safety or labeling of generic metoclopramide.

Likewise, no duty arises based upon Wyeth and Schwarz's position as name brand manufacturers, or NDA or Reference Listed Drug holders. No federal statute or FDA regulation imposes a duty or suggests that a name brand manufacturer is responsible for the labeling of competing generic products. Indeed, Plaintiffs themselves argue that the FDA regulations confirm that name brand manufacturers and generic manufacturers are each responsible for their own respective drugs and labels. *See* 21 C.F.R. §§ 314.70(a)(1), 314.70(b)(2)(v)(A), 314.97, 314.98. Wyeth and Schwarz cannot effectuate a labeling change to the generic manufacturers' product labels. *See* 21 C.F.R. § 314.50(d)(5)(vi)(b); 21 C.F.R. § 314.71(a).

Next, Plaintiffs argue that summary judgment is premature because discovery of the prescribing physician may demonstrate that he relied upon Wyeth or Schwarz information. Plaintiffs fail, though, to make the necessary showing to continue or delay summary judgment based upon allegedly necessary discovery. A party opposing summary judgment cannot wait until the eve of the summary-judgment hearing to claim that discovery is necessary and "should show by affidavit the existence and availability of additional evidentiary matter, what it is and its materiality, what steps have been taken to obtain it, and that failure to have obtained such evidence sooner did not result from inexcusable delay." *See Periera v. Fla. Power & Light Co.,* 680 So. 2d 617, 618 (Fla. 4th DCA 1996). When the plaintiff fails to make that showing and waits until shortly before the summary-judgment hearing to raise the issue or seek discovery, then summary judgment is warranted. *See id.* (affirming the ruling that a plaintiff could not avoid summary judgment by seeking discovery "three days before the summary judgment hearing."); *see also Muth v. AIU Ins. Co.,* 982 So. 2d 749, 750 (Fla. 4th DCA 2008) (noting with approval the granting of summary judgment when the plaintiff failed to meet the *Periera* standard).

Here, Wyeth and Schwarz served their motion for summary judgment on August 31, 2009. Plaintiffs waited nearly three months, until this Court's deadline to submit their opposition to Defendants' motion on November 25 (five court days before the summary-judgment hearing), to even raise the issue. Plaintiffs did so only in their memorandum opposing Defendants' motion, never actually pursued such discovery, and made no showing towards meeting the *Periera* standard. Plaintiffs' argument is both untimely and insufficient.

Even if Plaintiffs made any timely showing in support of their discovery argument, that argument does nothing to preclude summary judgment because discovery of the prescribing physician is "immaterial to the dispositive issue [] in the case." *Crespo v. Fla. Entm't Direct Support Org., Inc.,* 674 So. 2d 154, 155 (Fla. 3d DCA 1996) (*citing Amjad Munim, M.D. v. Azar,* 648 So. 2d 145, 151 (Fla. 4th DCA 1994)). For purposes of the issue before this Court upon Defendants' motion, the alleged reliance of the prescribing physician is presumed. Even presuming that Mrs. Dietrich's prescribing physician did rely upon Wyeth or Schwarz information, *Engle* still negates liability for Wyeth and Schwarz.

In *Engle,* the jury returned a verdict that the defendants made fraudulent and negligent misrepresentations, conspired to misrepresent or conceal information, intended that plaintiffs would rely upon the misrepresentations, that the individual plaintiffs relied upon those representations, and suffered injury as a result. *See Engle,* 945 So. 2d at 1255, 1256-57, n.4 (setting forth the issues presented to the jury and the jury's findings in favor of the class members in Phase I of the trial, as well as the jury's verdict for the individual plaintiffs in Phase II-A). Nonetheless, the Court held as a matter of law that the defendants whose products were not used by the individual plaintiffs could not be liable for those misrepresentations. *See id.* at 1276 (directing reversal of judgments against those defendants).

Engle produces the same result here. The issue before the Court is the question of duty, an issue of law, and the discovery that Plaintiffs raise would not create an issue of fact relative to that issue of law. *See Austin v. Mylander,* 717 So. 2d 1073, 1075 (Fla. 5th DCA 1998) (summary judgment proper when the court ruled as a matter of law that defendant breached no duty because any "factual issue was immaterial"). In turn, "when the non-moving party seeks to undertake discovery in support of a position which is not legally valid, it is not improper for the trial court to enter summary judgment before that discovery is complete." *A & B Discount Lumber & Supply, Inc. v. Mitchell,* 799 So. 2d 301, 303 (Fla. 5th DCA 2001). Plaintiffs' position on Defendants' liability is not legally valid under Florida law on duty or causation even presuming reliance by Mrs. Dietrich's prescribing physician.

Next, Plaintiffs advance a component-part doctrine argument claiming that the label for name brand Reglan® is a component part of the allegedly defective product, generic metoclopramide. No court applying Florida law has ever held that one manufacturer's label is a component part of another manufacturer's product, especially when that other manufacturer's product has its own label. Rather, the doctrine applies when a component part is "integrated into the final unit." *Scheman-Gonzalez v. Saber Mfg. Co.,* 816 So. 2d 1133, 1141 (Fla. 4th DCA 2002); *see* The Honorable Thomas D. Sawaya, *Florida Personal Injury Law & Practice with Wrongful Death Actions* § 13.7D. (2007-08) (Florida law applies the component-part doctrine to "component parts made by different suppliers and delivered to the manufacturer of the defective product who assembles them to produce its own product."). That is not the case here. There is no showing, let alone an issue of material fact, that Wyeth and Schwarz integrated or delivered anything to their generic competitors for manufacturing and labeling, let alone participated in that manufacturing and labeling. On the contrary, each manufacturer, both name brand and generic, is responsible for its own, and only its own, label.

Next, Plaintiffs argue that if this Motion is granted they may lack a remedy because the generic manufacturer defendants may have valid defenses. Plaintiffs have asserted and continue to assert, however, cognizable causes of action against the generic manufacturer defendants. Moreover, whether or not those other defendants possess valid defenses has no bearing on the fundamental point that Plaintiffs' claims against Wyeth and Schwarz lack any basis or support under Florida law.

Finally, as support for their theory of name brand liability, Plaintiffs rely upon a lone case from a California intermediate appellate court, *Conte v. Wyeth,* A116707, A117353, 2008 WL 4823066 (Cal. Ct. App. Nov. 7, 2008), as the only decision supporting their position. In fact, *Conte* is the lone outlier against the overwhelming weight of authority on this point. As of the

date of the summary-judgment hearing here, thirty-four decisions had applied the laws of twenty different states to hold that name brand manufacturers are not liable for injuries caused by generic products. Of those decisions, twenty-five in seventeen states reached that holding as to Wyeth and/or Schwarz - that neither one, as the manufacturers of name brand Reglan®, are liable for the injuries caused by their competitors' generic metoclopramide.[5] No case before or after *Conte* has agreed with its reasoning. Of the cases after *Conte* to address this issue, all ten courts, including most recently the United States Court of Appeals for the Eighth Circuit in *Mensing v. Wyeth, Inc.,* No. 08-3850, 2009 WL 4111209 (8th Cir. Nov. 27, 2009), have refused to follow *Conte.*

Importantly, *Conte* bears no resemblance to Florida law, particularly on the issues of duty and foreseeability. Conte recognized a tort based on Restatement (Second) of Torts section 311. No Florida court has ever adopted section 311. *Conte* imposed liability for a product's warnings even when the plaintiff never used that product. Florida law forbids liability under those circumstances. *See Engle,* 945 So. 2d at 1276; *Conley,* 570 So. 2d at 286. Finally, *Conte* imposed that liability in the same context as alleged here, for the information and label disseminated by Wyeth and/or Schwarz for name brand Reglan® when the plaintiff used only generic metoclopramide. Nothing in Florida law follows suit. This Court, or any lower Florida court applying *Engle* or *Conley,* could not reach the decision reached in *Conte.*

In reality, Plaintiffs' arguments and theories seek to dramatically expand Florida tort and product-liability law. Trial courts, though, are bound by existing law and "do not create precedent." *See Wood v. Fraser,* 677 So. 2d 15, 19 (Fla. 2d DCA 1996) (quoting *State v. Bamber,* 592 So. 2d 1129, 1132 (Fla. 2d DCA 1991)); *see generally Hernandez v. Garwood,* 390 So. 2d 357, 359 (Fla. 1980) (trial court not "free to disregard" higher authority). This Court's role is to apply that precedent. Here, it is bound by established Florida law on duty, causation, and product use, all of which contradict Plaintiffs' expansive and unsupported theories of liability. The expansion of Florida law that Plaintiffs seek is not a matter for a trial court or even the district courts of appeal, but for the Supreme Court of Florida. *See Hoffman v. Jones,* 280 So. 2d 431, 433-34 (Fla. 1973) (holding that the decision on appeal, from the Fourth District Court of Appeal, "exceeded its authority" by attempting to overrule the Court's precedent and establish a new test); *see also Reichhold Chems., Inc. v. Omni-Vest, Inc.,* 352 So. 2d 58, 59 (Fla. 1st DCA 1977) ("District courts in Florida have been directed in no uncertain terms to leave all judicial changes in the law to the Supreme Court of Florida."). Plaintiffs' causes of action cannot proceed against these Defendants.

Based upon the foregoing, it is

ORDERED AND ADJUDGED that Defendants' motion for summary judgment is hereby GRANTED in its entirety and final judgment be and is hereby ENTERED in favor of defendants Wyeth, Wyeth Pharmaceuticals, Inc., and Schwarz Pharma, Inc. Plaintiffs shall take nothing against Defendants Wyeth, Wyeth Pharmaceuticals, Inc., and Schwarz Pharma, Inc., who shall go hence without delay.

DONE AND ORDERED at West Palm Beach, Florida, this ___ day of December, 2009.

.....

ROBIN ROSENBERG, CIRCUIT JUDGE

Copies furnished:

Edward W. Gerecke

Steven R. Maher

C. Howard Hunter

Craig G. Sulton, D.O.

William J. Judge/Nancy Stewig

Footnotes

1 Plaintiffs make allegations in Counts I-V that are styled against all of the "Drug Company Defendants," including defendants other than Wyeth and Schwarz.

2 Federal courts applying Florida law also reach this holding. *See, e.g., Ugaz v. Am. Airlines, Inc.,* 576 F. Supp. 2d 1354, 1375 (S.D. Fla. 2008) ("whether a plaintiff proceeds under a negligence theory or a strict liability theory of products liability, the proper defendants are the manufacturers and perhaps other persons in the chain of distribution."); *Pulte Home Corp. v. Ply Gem Indus., Inc.,* 804 F. Supp. 1471, 1484-85 (M.D. Fla. 1992) ("it is well established under Florida law and elsewhere that identification of the product that caused the harm as the one sold or manufactured by the defendant is an essential element of traditional tort law.").

3 While of course not binding on this Court, the decision in *Sharp* is persuasive authority that assists this Court in independently exercising its judgment. *See McGauley v. Goldstein,* 653 So. 2d 1108, 1109 (Fla. 4th DCA 1995).

4 *See also Swett v. United States,* No. 8:06-CIV-1805-T-24TGW, 2007 WL 1017644, *3 (M.D. Fla. Mar. 30, 2007) (requiring "that the defendant's conduct created or controlled the risk.").

5 The complete list of these decisions can be found in Wyeth and Schwarz's memorandum of law in support of summary judgment dated November 25, 2009.

2008 WL 5592753 (N.J.Super.L.) (Trial Order)
Superior Court of New Jersey, Law Division.
Middlesex County

Thomas WESTERLUND, et al., Plaintiffs,
v.
WYETH, INC., a/k/a Wyeth Company f/k/a American Home Products Corporation, et al., Defendants.

No. MID-2174-05.
October 20, 2008.

Civil Action

Order Granting Defendant Wyeth's Motion for Summary Judgment for Lack of Product Identification

Reed Smith LLP, Formed in the State of Delaware, Princeton Forrestal Village, 136 Main Street, Suite 250, Princeton, New Jersey 08540-7839, (609) 987-0050, Fax: (609) 951-0824, Attorneys for Wyeth.

Honorable Heidi Willis Currier, J.S.C.

This matter having been opened to the Court by Defendant Wyeth, through its counsel, Reed Smith LLP, by way of motion for summary judgment against Plaintiffs; and in the presence of counsel for Plaintiffs and counsel for the other defendants; and the Court having considered the papers filed, the opposition thereto, if any and for other good cause shown,

IT IS on this 20 day of October, 2008, ORDERED that:

1. The motion for summary judgment filed by Defendant Wyeth is hereby GRANTED; and

2. All claims against Defendant Wyeth in Plaintiffs' First Amended Complaint are dismissed with prejudice and without costs to either party; and

3. A copy of this Order shall be served upon all parties within seven (7) days of moving counsel's receipt of same.

<<signature>>

The Honorable Heidi Willis Currier, J.S.C.

X opposed

_____ unopposed

Written decision mailed to parties.

Argued: October 10, 2008

Decided: October 20, 2008

Counsel for Plaintiffs:

Steven Pontell, Esq. of Verde, Steinberg & Pontell, LLC

Kenneth C. Gilman, Esq. of Gilman and Pastor, LLP

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Camilla Lee, Esq. of McKenna, Long & Aldridge, LLP

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Thomas D. Robertson, Esq. of Sedgewick, Detert, Moran & Arnold, LLP

CURRIER, J.S.C,

INTRODUCTION

There are two pending motions in this ease. Defendant Wyeth filed a Motion for Summary Judgment. Plaintiffs subsequently filed a Motion for Leave to File a Second Amended Complaint. The court heard oral arguments on both motions on October 10, 2008 and a Statement of Facts was also placed on the record at that time.

Defendant Wyeth's Motion for Summary Judgment

Summary Judgment is only appropriate where "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to judgment as a matter of law." *N.J. Court Rules R.* 4:46-2(c). In determining whether an issue is material, the focus is on "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Brill v. the Guardian Life Ins. Co. of America,* 142 N.J. 520, 533 (1995). After passage of "adequate time to complete the discovery, summary judgment should be granted "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial" *Id.* at 533.

The substance of Wyeth's Motion is that Plaintiffs have not shown that any of the named Plaintiffs ever took Wyeth's drug-Cordarone. Plaintiffs have conceded in their papers that the named plaintiffs cannot prove conclusively that they ingested Wyeth's brand Cordarone drug. In New Jersey it is a fundamental principle of product liability law that a plaintiff must prove as an essential element of his case that the defendant manufacturer actually made the particular product which caused the injury. *Namm v. Charles E. Frosst Company,* 178 N.J. Super. 19 (App. Div. 1981). Plaintiffs must show that they have ingested or used Wyeth's Amiodarone drug-Cordarone.

Plaintiffs argue that liability can be established against Wyeth even if plaintiffs did not use the Wyeth Corderone product. The theory espoused is that of innovator liability in. which the initial manufacturer (innovator) is liable for harm caused by a plaintiffs ingestion of a competitor's or generic version of the drug if the innovator negligently marketed the product.

That is not the current law in New Jersey. The Court declines to extend the law in this field and is not accepting that argument in this case today.

Plaintiffs also urge this Court to accept an unpublished Pennsylvania Court of Common Pleas case which used Pennsylvania law to support the theory that a drug manufacturer can incur liability even where its product was not used.

That case of course is not binding on this Court and this Court does not find it to be of any persuasive weight. There are no similarities between Pennsylvania and New Jersey law in this area of the law. Pennsylvania does not have a Products Liability Act and our courts have been very clear that the Products Liability Act is New Jersey's exclusive remedy for harm caused by a product. Therefore the Court rejects that claim.

The five named plaintiffs in this Complaint alleged to have claims against Wyeth. have presented no proofs that they used a Wyeth drug. To the contrary, the evidence shows that the named plaintiffs did not use a Wyeth product. There is no genuine issue of material fact.

Therefore Summary Judgment as to defendant Wyeth by plaintiffs O'Donnell, Jamieson, Muccino, Bryant and Westerlund is granted.

Plaintiff's Motion for leave to file a Second Amended Complaint

Plaintiffs, presumably in response to the Summary Judgment Motion of Wyeth have filed a Motion to leave to file an amended Complaint. Plaintiffs seek to file a Second Amended Complaint with several changes from the original Complaint. First, as a result of *Sinclair v. Merck and Company,* 195 N.J. 51 (2006), plaintiffs have limited and narrowed the requested remedy to each of the named Plaintiffs and class members who sustained manifest physical injury. Also because of *Sinclair,* Plaintiffs have removed their causes of action for negligence, fraud, and violation of the N.J. Consumer Fraud Act, as *Sinclair* states these are subsumed by the Products Liability Act. Third, Plaintiffs have withdrawn their claim for punitive damages.

Most importantly to this motion, Plaintiff seeks to intervene and add several Plaintiffs, including James Lockwood, Martha Andreason, Mary Hoffman, Fred Arters, Joan Bohl, Ray Watson, and Richard Russell. These additional plaintiffs have allegedly produced medical records concerning use of Amiodarone. Plaintiffs claim that they have proofs that Lockwood and Andreason ingested Wyeth's Amiodarone, Cordarone brand. Wyeth claims there are no proofs presented by plaintiffs that Andreason ingested Cordarone.

Plaintiffs assert that proposed plaintiffs Fred Arters, Mary Hoffman executrix for deceased Louis Hoffman, and Joan Bohl, executrix for deceased William Bohl, ingested Eon's Amiodarone. They argue these new plaintiffs are necessary to avoid a Summary Judgment Motion on behalf of Eon. In addition, plaintiffs argue that to comply with Judge Kieser's Order of April 7, 2008 plaintiffs Artis and Hoffman are needed as individuals who suffered certain ailments allegedly as a result of the use of the Eon drug amiodarone.

Courts have held that adding additional class representatives is premature prior to certification of a class or prior to even filing a motion for class certification. *Bailey v. Cumberland Cas & Surety Co.,* 180 Fed. Appx. 862 (11th Cir. 2006); *Dietrick v. Bauer,* 76 F.Supp. 2d 312 (S.D.N.Y. 1999). Two new proposed Plaintiffs, Ray Watson and Richard Russell, are alleged by Plaintiffs to have taken Upsher-Smith's drug. The Court finds these additions are duplicative. There already exist plaintiffs in this complaint, including Muccino, Bryant, and Andreason, who allege they have taken Upsher's drug. The addition of Watson and Russell serves no purpose, as this is not a class action.

Under R. 4:9-1, leave of court to amend pleadings "shall be freely given when justice requires". See *Kernan v. One Washington Park Urban Renewal Associates,* 154 N.J. 437, 457 (1998). The Amended Complaint must not be proposed to delay or for any other improper purpose, but to properly further the interests of the named Plaintiffs and proposed class by providing Plaintiff's which will allow the action to proceed. To date, there has been one prior amendment.

Under New Jersey procedural law, an amendment relates back "whenever the claim or defense asserted in the amended pleading arose out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading." N.J. Court Rules, 1969 R 4:9-3 (2005). The New Jersey Supreme Court has stated that "where the amendment constitutes the same matter more fully or differently laid, or the gist of the action or the basic subject matter of the controversy remains the same, it should be readily allowed and the doctrine of relation back applied," *Kernan v. One Washington Park Urban Renewal Associates* 154 N.J. 437, 458 (1998). New Jersey courts have recognized that amended complaints relate back even when the initial complaint was subject to dismissal *Notte v. Merchant's Mutual Insurance Co.,* 185 N.J. 490 (2006). This Amended Complaint unquestionably "relates back" because it is essentially the same claim only with different plaintiffs.

Wyeth responds by asserting that Wyeth is prejudiced by undertaking four years of unnecessary litigation unnecessary motion practice, Wyeth claims that plaintiffs have failed to address the issue of product identification numerous times and should not be allowed to amend their complaint just to avoid Wyeth's Summary Judgment motion, However, the Court finds that despite four years of this case in litigation that very little has been done. The Court finds that at this stage in the litigation that Wyeth is not prejudiced.

Wyeth also claims that like in the initial Complaint proposed Plaintiffs Andreason and Hoffman have not provided sufficient proof that they ingested Wyeth's version of Amiodarone Cardarone. Wyeth claims that without the pharmacy dispensing records, there is no proof that Wyeth's Amiodarone was ever ingested.

Courts have denied motions for leave to amend where the amendment is futile, *Interchange State Bank v. Rinaldi,* 303 N.J. Super. 239, 257 (App. Div. 1997). The Court finds that based on the prior pleadings in this case now having been found to be insufficient because of the lack of proofs by all the original plaintiffs against defendant Wyeth and Summary Judgment now having been granted and four years having passed since the initial Complaint, that plaintiff must provide this Court with proofs at this time to amend this Complaint to name new plaintiffs against Wyeth and to show that this amendment would not be futile. They can only provide sufficient proofs at this time as to Lockwood.

Based on the above caselaw and the particular circumstances of this case the Court denies the Motion to Amend the Complaint to add plaintiff Hoffman against Wyeth. The Motion to Amend is granted as to the addition of plaintiff Lockwood. With regard to proposed plaintiff Andreason, plaintiffs counsel must provide proofs to defendant Wyeth within 60 days of this Order that show Andreason to have ingested Wyeth's Cordarone. The parties will advise the Court whether those proofs have been provided and whether they are sufficient. Thereafter, the Court will issue an Amended Order if appropriate.

Plaintiffs seek to add Artis, Hoffman and Bohl against Eon. Again, the medical records produced do not substantiate Artis and Hoffman to have ingested an Eon drug. After four years plaintiffs must have evidence to support their pleadings to add new plaintiffs against these defendants particularly in light of the circumstances of this case. Motions have been filed several times as to product identification issues. The Court denies the amendment of the Complaint to include Artis and Hoffman against Eon. The Complaint may be amended as to plaintiff Bohl against Eon. If, within 60 days of the date of this Order, plaintiffs can provide proofs to Eon with respect to Artis and Hoffman, and the Court is so advised, the Court will issue an amended Order if appropriate,

Lastly, plaintiffs seek to add four new plaintiffs against Upsher-Smith. The Court does not find there is any basis to do so. It is not proper at this point to add new class representatives and there has been no motion filed by Upsher-Smith as to product

identification issues by the original plaintiffs. There is no basis for the addition of those plaintiffs against Upsher-Smith at this time. The motion to Amend the Complaint to add those plaintiffs against Upsher-Smith is denied.

End of Document

2020 WL 1974190
Only the Westlaw citation is currently available.
United States District Court, W.D. Wisconsin.

Dewane D. FRASE, as Special Administrator of the Estate of Douglas Frase, and Carol L. Frase, Plaintiffs,
v.
ASHLAND CHEMICAL CO. DIVISION OF ASHLAND, INC., et al., Defendants.

19-cv-273-wmc
|
Signed 04/24/2020

Attorneys and Law Firms

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Dennis M. Sullivan, Michael A. Hughes, Chilton Yambert & Porter, LLP, Madison, WI, Larry J. Chilton, Chilton Yambert Porter LLP, Chicago, IL, for Defendants Ashland Chemical Company Division of Ashland, Inc., BP Products North America, Inc., Exxon Mobil Corporation, Shell Oil Company, Union Oil Company of California.

Dennis M. Sullivan, Chilton Yambert & Porter, LLP, Madison, WI, for Defendant Sunoco (R&M), LLC.

OPINION AND ORDER

WILLIAM M. CONLEY, District Judge

***1** In this products liability action, plaintiffs claim that Douglas Frase died as a result of his exposure to certain "benzene-containing materials" during the course of his employment at a tire plant. Plaintiffs have now filed suit against various named defendants and ninety-five unnamed defendants, alleging claims of strict liability, negligence, and failure to warn. Before the court are the named defendants' motions to dismiss the case for failure to state a claim. (Dkts. #4, 6, 7, 19, 13.) Also before the court is plaintiffs' motion to seek leave to file a second amended complaint. (Dkt. #52.) For the reasons discussed below, the court will deny plaintiffs' motion and grant defendants' motions in part, while providing plaintiffs a limited opportunity to amend the deficiencies identified in their complaint.

BACKGROUND

A. Parties

Pursuant to Wis. Stat. § 895.04, plaintiff Dewane Frase brings this suit as special administrator of the Estate of Douglas Frase, and plaintiff Carole Frase brings suit as Douglas Frase's surviving spouse. The court will refer to plaintiffs by their full names, while referring to decedent Douglas Frase simply as "Mr. Frase" or "Frase."

Initially, plaintiffs sued nine, named defendants and ninety-five fictitious defendants curiously denominated "defendants 5 through 100." As discussed in greater depth in the procedural history section below, plaintiffs later amended their complaint, effectively dismissing four of the named defendants, but then tried to add those same defendants back in by moving to file another amended complaint. These four, dismissed defendants are Four Star Oil and Gas Company (f/k/a Getty Oil Company), Shell Chemical L.P., Sunoco, Inc. (R & M), [1] and Texaco Downstream Properties, Inc. -- and will be referred to here as the

"Group A defendants." The remaining five defendants are Ashland Chemical Company Division of Ashland, Inc., BP Products North American, Inc., Exxon Mobil Corporation, Shell Oil Company, and Union Oil Company of California d/b/a/ Unocal Corporation -- referred to here as the "Group B defendants."

B. Basic Fact Allegations

From approximately 1952 until 1992, Mr. Frase was employed at a tire manufacturing facility operated by The Uniroyal Goodrich Tire Company, Inc. ("the Uniroyal plant"). During those forty years, Frase worked in multiple departments and positions at the Uniroyal plant, including tire builder and/or loader, treadman, assembly and installation, storing and curing, and conveyer attendant.

On April 1, 2016, Frase was diagnosed with Mylodysplastic Syndrome ("MDS"), from which he died approximately seven months later, on November 7. Plaintiffs assert that Frase's death was a "direct and proximate result of [his] exposure to Defendants' Benzene-Containing Materials." (Compl. (dkt. #1-2) ¶ 4.) Plaintiffs define "Defendants' Benzene-Containing Materials" as "benzene, benzene derivatives, rubber solvents, solvent blends, and other toxic and hazardous chemicals" that defendants, "and/or their predecessor or successors in interest," "designed, produced, manufactured, distributed, sold, supplied, delivered, handled, marketed, advertised, instructed, and/or placed into the stream of commerce." (*Id.* ¶¶ 1, 3.) In their complaint, plaintiffs allege three, formal legal grounds for liability against each of the named and unnamed defendants for negligence, strict liability, and failure to warn. (*Id.* at 7-12.)

C. Procedural Background

***2** Plaintiffs originally filed this action in state court on December 28, 2018. While still in state court, the Group A defendants filed motions to dismiss plaintiffs' complaint due to improper service and lack of personal jurisdiction. Before these dismissal motions were briefed or resolved in state court, however, the Group B defendants filed a notice of removal to federal court asserting complete diversity between plaintiffs and all named defendants. (Notice of Removal (dkt. #1).) The Group B defendants argued that the Group A defendants did not need to consent to removal because they were not properly served. (*Id.* ¶ 11 (citing 28 U.S.C. § 1446(b)(2)(A)) ("[A]ll defendants who have been properly joined and served must join in or consent to the removal of the action.").) The Group B defendants also indicated that they would file a separate consent to removal "to the extent necessary and limited solely to the issue of removal." (*Id.* ¶¶ 15, 20.)

All defendants then moved to dismiss the complaint for failure to state a claim on April 11, 2019. (Dkts. #4, 6-13.) While each defendant filed a separate motion, they all adopted and incorporated the bases set forth in defendant Ashland's brief in support of its motion to dismiss. (Dkts. #6-13.) These motions were also fully briefed and came under advisement on May 13, 2019.

On May 16, 2019, it came to the attention of this court that the Group A defendants' motions to dismiss for lack of jurisdiction and improper service previously filed in state court remained unresolved, as well as unbriefed. (Dkt. #24.) The court then directed the Group A defendants to refile their motions so that they could be tracked by the CM/ECF system (previously, they were attached as exhibits to the notice of removal) and set a briefing schedule. (Dkt. #24.) Rather than filing an opposition brief to these jurisdictional motions, however, plaintiffs filed a notice, which purported to dismiss the Group A defendants under Federal Rule of Civil Procedure 41(a). (Dkt. #41.) Because Rule 41(a) is limited to dismissals of an entire case, the court construed plaintiffs' notice as a motion to amend their complaint and permitted them to dismiss the Group A defendants without prejudice under Rule 15(a)(2). (June 4, 2019 Order.) [2]

On July 24, 2019, without motion or explanation, plaintiffs next filed an amended complaint in which they named all of the original defendants, including the previously dismissed Group A defendants. (Dkt. #45.) In response to the court's inquiry (dkt. #46), plaintiffs explained that their plan all along had been to dismiss the Group A defendants, then to file an amended complaint adding them back in to perfect service (dkt. #47). The court subsequently ordered plaintiffs to file a motion to seek leave to file their amended complaint. (Dkt. #49.) Plaintiffs have now done so. (Dkt. #52.)

OPINION

I. Motion to Dismiss

A motion to dismiss under Rule 12(b)(6) is designed to test the complaint's legal sufficiency. *See* Fed. R. Civ. P. 12(b)(6). "A defendant is owed 'fair notice of what the ... claim is and the grounds upon which it rests.' " *Bissessur v. Indiana Univ. Bd. of Trustees*, 581 F.3d 599, 602 (7th Cir. 2009) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). However, dismissal is only warranted if no recourse could be granted under any set of facts consistent with the allegations. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The complaint must contain "enough facts to state a claim to relief that is plausible on its face" and also must state sufficient facts to raise a plaintiff's right to relief above the speculative level. *Twombly*, 550 U.S. at 557. "A claim has facial plausibility 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.' " *Bissessur*, 581 F.3d at 602 (quoting *Iqbal*, 556 U.S. at 678).

A. Failure to Identify the Product

***3** Although defendants proffer numerous arguments as to the complaint's legal deficiencies, the court begins with defendants' broadest -- that none of plaintiffs' claims meet the requirements of Wis. Stat. § 895.046, and accordingly should be dismissed. (Ashland Br. (dkt. #5) 9.)

In 2011, the Wisconsin Legislature enacted Wisconsin Act 2, which both codified and made various changes to products liability actions in Wisconsin. *See* 2011 Wis. Act 2, §§ 29-31, 45(5) (codified at Wis. Stat. § 895.046). Section 895.046 applies to:

> all actions in law or equity ... in which a claimant alleges that the manufacturer, distributor, seller, or promoter of a product is liable for an injury or harm to a person or property, including actions based on allegations that the design, manufacture, distribution, sale, or promotion of, or instructions or warnings about, a product caused or contributed to a personal injury or harm to a person or property, a private nuisance, or a public nuisance, and to all related or independent claims, including unjust enrichment, restitution, or indemnification.

Wis. Stat. § 895.046(2).

As an initial matter, the court finds that § 896.046 governs all of plaintiffs' claims. Plaintiffs acknowledge as much in their complaint by announcing this to be a "product liability action" based on Frase's exposure to products "designed, produced, manufactured, distributed, sold, supplied, delivered, handled, marketed, advertised, instructed, and/or placed into the stream of commerce" by the defendants. (Compl. (dkt. #1-2) ¶ 1.) While plaintiffs do not cite § 896.046 in their complaint, neither do they appear to dispute that section governs their claims (*see generally* Pls.' Opp'n (dkt. #19)), nor could they. Rather, comparing plaintiffs' claims to the actions described in § 895.046(2), their claims fall easily within the ambit of that subsection and are, therefore, governed by § 896.046.

The next question for the court is what factual allegations does § 896.046 require of plaintiffs. The regime outlined in § 896.046 contemplates that a products liability claim may proceed under one of two liability theories. Under the first, the plaintiff must "prove[ ], in addition to any other elements required to prove his or her claim, that the manufacturer, distributor, seller, or promoter of a product manufactured, distributed, sold, or promoted the specific product alleged to have caused the claimant's injury or harm." Wis. Stat. § 895.046(3). If a plaintiff "cannot meet the burden of proof under [§ 895.046(3)]," then he may proceed under a second, "risk-contribution" theory. § 895.046(4). Under this latter approach, the plaintiff need not identify the specific product alleged to have caused his injury, but must meet a number of other specific requirements. Wis. Stat. § 895.046(4).

Since plaintiffs expressly disavow bringing their claims "under the Risk-Contribution Theory of Wis. Stat. § 895.046(4)" (Pls.' Opp'n (dkt. #19) 7 n.3), the key here becomes whether plaintiffs have met the statutory requirements outlined in subsection § 895.046(3).

Defendants maintain in their motions to dismiss that plaintiffs have not because they failed to identify the specific product alleged to have caused Frase's death. (*See, e.g.*, Ashland Br. (dkt. #5) 10.) At least as currently pled, the court agrees that plaintiffs' claims are too vague to provide defendants fair notice of their claims or to plausibly state a claim under § 895.046(3). Indeed, the products identified in plaintiffs' complaint are "benzene, benzene derivatives, rubber solvents, solvent blends, and other toxic and hazardous chemicals" that defendants "and/or their predecessor or successors in interest" "designed, produced, manufactured, distributed, sold, supplied, delivered, handled, marketed, advertised, instructed, and/or placed into the stream of commerce." (Compl. (dkt. #10) ¶¶ 1, 3.)

***4** Even if the laundry list of benzene, benzene derivatives and rubber solvents and blends were sufficient, plaintiffs' inclusion of "other toxic and hazardous chemicals" as one of "products" at issue is on its face impossibly broad. Plaintiffs provide no definition or limitation on what they consider a "toxic" or "hazardous" chemical to be, and the dictionary definitions are, respectively, "containing or being poisonous material especially when capable of causing death or serious debilitation" and "involving or exposing one to risk (as of loss or harm)." *Toxic*, Merriam-Webster (Feb. 26, 2020) https://www.merriam-webster.com/dictionary/toxic; *Hazardous*, Merriam-Webster (Mar. 8, 2020) https://www.merriam-webster.com/dictionary/hazardous. As such, defendants plausibly argue that plaintiffs' allegations could cover the entire range of their product lines. (Ashland Br. (dkt. #5) 4.)

Defendants also argue that plaintiffs' allegations regarding "rubber solvents" and "solvent blends" are similarly vague, explaining that:

> A solvent has been defined as "a substance that dissolves another to form a solution." The Random House Dictionary of the English Language 1818 (Unabr. 2d ed. 1987) (identifying water as "a solvent for sugar"). Therefore, a "rubber solvent" could be any product that dissolves rubber and a "solvent blend" is nothing more than a mixture capable of dissolving another substance.

(Ashland Br. (dkt. #5) 12.)

In fairness to plaintiffs, the court recognizes that this argument may be somewhat disingenuous in light of their acknowledgement that Uniroyal maintained specific codes for "Rubber Solvent" and "Solvent Blends." (*See, e.g.,* Ashland Reply (dkt. #21) 15 ("The Uniroyal code for 'Rubber Solvent' was SO-124 (later SV-797) and the code for 'Solvent Blend' was SO-149 (later SV-749).").) Still, plaintiffs' counsel also seemed to be aware of these specific codes -- as plaintiffs cited them in their opposition brief -- yet failed to include the product codes in their complaint. (Pls.' Opp'n (dkt. #19) 5.) The Seventh Circuit has cautioned that "[a]n inadequate complaint will not survive a motion to dismiss simply because the defendants managed to figure out the basic factual or legal grounds for the claims." *Adams v. City of Indianapolis*, 742 F.3d 720, 729 (7th Cir. 2014).

Along these same lines, plaintiffs argue that "Defendants know, or can easily identify from their sales records, which of their rubber solvent and solvent blend products they sold to the Uniroyal Plant during the time Douglas Frase was employed." (Pls.' Opp'n (dkt. #19) 6.) But this implies that the products at issue are only rubber solvent and solvent blends directly sold by defendants to Uniroyal from 1952-92, which is in fact a *much* narrower set of products than those vaguely alleged in the complaint. In another products liability case, the Wisconsin Supreme Court refused to accept plaintiff's argument that "residential paint pigment" was actually the product in question when the complaint referenced only "white lead carbonate," "white lead pigment," and "white lead carbonate pigment." *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 2009 WI 78, ¶ 22, 319 Wis. 2d 91, 768 N.W.2d 674. The court reasoned that "[a] liberal pleading standard cannot transform a complaint regarding 'white lead carbonate pigment' into one regarding 'residential paint pigment.' " *Id.* ¶ 21. Similarly, plaintiffs here cannot expect this court to narrow their broad allegations regarding "benzene, benzene derivatives, rubber solvents, solvent blends, and other toxic and hazardous chemicals" that defendants ("and/or their predecessor or successors in interest")

"designed, produced, manufactured, distributed, sold, supplied, delivered, handled, marketed, advertised, instructed, and/or placed into the stream of commerce" to just "rubber solvent and solvent blend products sold by defendants to the Uniroyal plant between 1952 and 1992."

***5** Nevertheless, plaintiffs point to two other cases involving similar claims for support: *Christ v. Exxon Mobil Corp., Eau Claire Co.*, (Wis.) Case No. 06 CV 420, and *Beaver v. Exxon Mobil Corp., Eau Claire Co.*, (Wis.) Case No. 09 CV 621. [3] Plaintiffs argue these cases involved "identical causes of action" against the same defendants, demonstrating that defendants have "actual knowledge regarding the identity of the specific solvent products at issue." (Pls.' Opp'n (dkt. #19) 4.) There are any number of problems with this argument. To begin, defendants in these cases did *not* move to dismiss the suits for failure to state a claim. Accordingly, even if plaintiffs here are asserting identical vague allegations as to the products at issue to those made in *Christ* and *Beaver*, those cases provide no helpful precedent in resolving the pending motions to dismiss, nor relieve this court of its duty to assess the adequacy of those allegations. Moreover, *Christ* and *Beaver* were filed in 2006 and 2008, respectively, which predated the passage of Wisconsin Act 2, which, as noted above, codified the requirement that a plaintiff's products liability claim must "prove[ ], in addition to any other elements required to prove his or her claim" that a defendant "manufactured, distributed, sold, or promoted the specific product alleged to have caused the claimant's injury or harm." Wis. Stat. § 895.046(3).

Even before the Legislature's 2011 enactment of Act 2, the Wisconsin Supreme Court cautioned that "in a products liability case, the plaintiff must -- at minimum -- identify the product alleged to be defective. Doing so puts the defendant on notice and allows the defendant to begin building a defense." *Godoy ex rel. Gramling*, 2009 WI ¶ 21. If anything, this is even more true after codification of the *Godoy* requirement in § 895.046(3). In particular, the "legislative findings and intent" introduction to § 895.046 indicates that the law was passed to narrow the Wisconsin Supreme Court's "improperly expansive application of the risk contribution theory of liability" and to "assure[ ] that businesses may conduct activities in this state without fear of being sued for indefinite claims of harm from products which businesses may never have manufactured, distributed, sold, or promoted, or which were made and sold decades ago." § 895.046(1g). While plaintiffs here do not pursue claims under the risk contribution theory, the fact that the Legislature passed Wis. Stat. § 895.046 in part to limit overbroad products liability claims provides useful guidance. Given this context, and the reasons discussed above, the court concludes that plaintiffs have failed to identify with adequate specificity the allegedly defective products at issue in this case.

In so ruling, the court recognizes that a products liability plaintiff will often need to conduct discovery in order to uncover the specific identity of the allegedly injurious product. *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809, 817 (E.D. Wis. 2015) (recognizing that formal discovery is often necessary in a products liability case "before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim"). However, this recognition does not permit a plaintiff to assert vague and implausible claims against as many products and as many defendants as it likes. As defendants persuasively argue here,

> [p]laintiffs' overly broad terminology places [defendants' entire] product inventory at issue because one or more of those products may have (1) been capable of dissolving rubber, (2) been capable of dissolving some other substance, (3) posed any type of physical hazard, (4) posed any type of health hazard or (5) been considered a poison.

(Ashland Br. (dkt. #5) 13.) Unfortunately, these broad category descriptions are an accurate summary of the vague allegations in plaintiffs' current pleading. These allegations neither provide defendants fair notice of the claims against them nor state a plausible claim. Accordingly, defendants' motion to dismiss plaintiffs' complaint will be granted.

The court hastens to add that this dismissal will be without prejudice. It will also include a brief tolling of any applicable statute of limitations *provided* plaintiffs take advantage of the opportunity to seek leave to file an amended complaint to cure

the problems identified above within twenty-one (21) days. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 562 (7th Cir. 2010) ("Generally, if a district court dismisses for failure to state a claim, the court should give the party one opportunity to try to cure the problem, even if the court is skeptical about the prospects for success."); *Shott v. Katz*, No. 15 C 4863, 2015 WL 6701795, at *5 (N.D. Ill. Nov. 2, 2015), *aff'd*, 829 F.3d 494 (7th Cir. 2016) (dismissing complaint without prejudice for failure to state a claim but giving plaintiff fourteen days to file an amended complaint). Further, plaintiffs do not get carte blanche to start from scratch. As discussed below, plaintiffs have specifically waived a number of claims and arguments that they will not be permitted to resurrect moving forward. Additionally, if plaintiffs do seek leave to file an amended complaint, the court would be willing to consider arguments by defendants that the costs and fees of litigating the first and second amended complaints should be imposed on plaintiffs or plaintiffs' counsel. Such an argument may be particularly apt if plaintiffs continue to attempt to rename the previously dismissed Group A defendants, given plaintiffs' inexplicable procedural missteps regarding their status in this case.

***6** Finally, the court will address defendants' remaining arguments regarding plaintiffs' claims to better guide plaintiffs and defendants as to other grounds raised for dismissal of the complaint.

B. Waived Claims

Although plaintiffs do not allege fraud in their formal counts, defendants note that one of plaintiffs' allegations could be read to suggest a fraud claim and then go on to argue that plaintiffs have failed to allege sufficient facts to adequately state such a claim. (Ashland Br. (dkt. #5) 3.) In their opposition brief, plaintiffs explain that they are *not* pursuing any fraud claims. (Pls.' Opp'n (dkt. #19) 7 n.3.) As discussed above, plaintiffs also confirm that they are not pursuing claims via the risk-contribution theory of liability under Wis. Stat. § 895.046(4). (*Id.*) Finally, plaintiffs specifically state that "benzene itself is not the product at issue." (*Id.* at 10.) Accordingly, the court will confirm that these claims and allegations -- to the extent they were asserted at all -- are dismissed with prejudice.

C. Remaining Arguments

1. Failure to Warn

Defendants also attack plaintiffs' failure-to-warn claims on the basis that Wisconsin law does not recognize such a cause of action. They write:

> Plaintiffs allege three separate causes of action under their "failure-to-warn" umbrella: negligence (Count I), strict liability (Count II) and failure to warn (Count III). Notwithstanding the fact that FHSA preempts state-law warning claims, Wisconsin only recognizes the first two counts as viable causes of action.

(Ashland Br. (dkt. #5) 9.) In support, defendants cite to *Kozlowski v. John E. Smith's Sons Co.*, 87 Wis. 2d 882, 898, 275 N.W.2d 915 (1979), and Wisconsin Jury Instructions 3242 and 3262. While these authorities do not *reject* failure-to-warn claims under Wisconsin law, they do suggest that such claims generally lie under a negligence or strict liability theory and, thus, at least overlap with the causes of action alleged in plaintiffs' complaint. Indeed, Wisconsin Jury Instruction 3242 is titled "negligence: duty of manufacturer (supplier) to warn" and Instruction 3262 is titled "strict liability: duty of manufacturer (supplier) to warn." Moreover, in *Kozlowski*, the supreme court analyzed a failure-to-warm claim under strict liability and negligence theories. 82 Wis. 2d at 898 ("[W]e will proceed to discuss whether on the basis of strict liability or common law negligence, Smith failed to warn of the alleged hazardous condition."). In sum, defendants own citations suggest that Wisconsin *does* recognize failure to warn claims, and the court will not dismiss any of plaintiffs' claims outright on this basis, while at the same time recognizing that they may overlap with plaintiffs' negligence and strict liability claims.

2. Failure to State a Claim for Manufacturing and Design Defects

Defendants next argue that plaintiffs have both failed to allege sufficient facts to support their claims of manufacturing and design defects. (Ashland Br. (dkt. #5) 16.) Plaintiffs complaint contains only two allegations regarding such defects: (1) "Defendants supplied products with marketing, design, and/or manufacturing defects" and (2) "The subject products were defective in their design, manufacture and/or warnings that accompanied them." (Compl. (dkt. #1-2) ¶¶ 35.h, 43.) These claims are indeed perfunctory. While lacking in detail, however, they also state plausible claims and are not so vague as to fail to provide basic notice to defendants. *See Garross*, 77 F. Supp. 3d at 817 (plaintiff's allegation that defendants' device "was defectively designed because the design was unsafe when used in the manner promoted by Defendants and in a manner reasonably foreseeable by the Defendants" sufficiently stated a claim). Whether there is any substance to the claim is a proper subject of discovery.

3. Preemption

***7** Defendants also argue that plaintiffs' failure-to-warn claims are preempted by the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. § 1261, *et seq.* (Ashland Br. (dkt. #5) 4-8.) Certainly, the FHSA may preempt a state law that "interfere[s] with, or [is] contrary to" it. *Aux Sable Liquid Prod. v. Murphy*, 526 F.3d 1028, 1032 (7th Cir. 2008) (internal citations and quotations omitted). "Pre-emption may be either express or implied." *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152 (1982). Here, the FHSA contains an express preemption clause, which provides:

> no state ... may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness unless such cautionary labeling requirement is identical to the labeling requirement under [this Act].

15 U.S.C. § 1261, note (b)(1)(A).

However, preemption is an affirmative defense, meaning *defendants* bear the burden of proving it. *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010). While the FHSA establishes cautionary labeling and warning requirements for certain hazardous products, 15 U.S.C. § 1261, *et seq.*, it only regulates products that are "intended, or packaged in a form suitable, for use in the household or by children." 15 U.S.C. § 1261(p).

Defendants argue that plaintiffs' allegations "cover the entire range of [defendants'] product line, including its retail consumer products." (Ashland Br. (dkt. #5) 4.) In particular, defendants point out that in plaintiffs' complaint, they allege:

> [n]either Decedent nor the average consumer of Defendants' products would have expected Defendants' products to contain carcinogenic chemicals, given the fact that they are *consumer-grade products* and do not carry warnings advising of the cancer risk on the product labels.

(*Id.* (citing Compl. (dkt. #1-2) ¶ 43).) Because, defendants argue, plaintiffs' allegations relate to products regulated by the FHSA, plaintiffs' failure-to-warn state law claims are preempted by the FHSA. (*Id.*) However, plaintiffs counter that the products at issue in this case were not subject to FHSA regulation because they are not "household products" under 15 U.S.C. § 1261(p). (Pls.' Opp'n (dkt. #19) 6.) More specifically, they point out that tire manufacturing is a "large-scale industrial process" and

that the "rubber solvent and/or solvent blend" products used in bulk at tire manufacturing facilities such as Uniroyal are "not intended nor suitable for use in the home by any reasonable stretch of the imagination." (*Id.* at 6-7.)

At this point, defendants have yet to prove that any of plaintiffs' claims are preempted. In fairness, plaintiffs' allegation that the products at issue are "consumer-grade products" does suggest that those products may be regulated by the FHSA. But only when a plaintiff "admits all the ingredients of an impenetrable defense" does he plead himself out of court. *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004). Here, that a product is "consumer-grade" does not necessarily mean that it was intended or packaged in a form suitable for use in the household such that it is regulated by the FHSA. *See Vinson v. Vermilion Cty., Illinois*, 776 F.3d 924, 929 (7th Cir. 2015) (plaintiff did not plead herself out of court when she alleged that the "complied" with a search, which did not prove that she *consented* to the search). Moreover, defendants' own arguments that plaintiffs' allegations include *all* of its products, including presumably non-household products, would suggest that plaintiffs' failure-to-warm claims are not necessarily preempted at least as to non-household products. Given the lack of clarity at this stage as to what products are at issue in this case, a decision as to preemption would be premature. Of course, defendants are free to argue otherwise at later stages in this litigation.

4. Defense under Wis. Stat. § 895.047(3)(d)

***8** Defendants similarly argue that plaintiffs have pleaded themselves out of court by alleging all the ingredients of the statutory defense provided under Wis. Stat. § 895.047(3)(d). That subsection states that:

> The court shall dismiss the claimant's action under this section if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.

Id.

Here, plaintiffs allege that "Benzene is a known human carcinogen and is a natural constituent of crude oil." (Compl. (dkt. #1-2) ¶ 2.) According to defendants "[b]y alleging that benzene is both an inherent characteristic of crude oil and a known carcinogen, Section 847.047(3)(d) requires dismissal of all their strict product liability claims." (Ashland Br. (dkt. #5) 19.) However, as discussed above, plaintiffs have also explained in their briefing that benzene itself isn't the *product* at issue, suggesting instead that benzene is a *component* of the alleged products. (Pls.' Opp'n (dkt. #19) 10.) Therefore, even if plaintiffs' allegations proved that an inherent characteristic of benzene was that it was carcinogenic and would be recognized by an ordinary person, this does not prove that the *product* at issue falls under the defense provided in Wis. Stat. § 895.047(3)(d). Regardless, this is a factual dispute that cannot ordinarily be resolved in a motion to dismiss.

II. Motion for leave to file second amended complaint

The court will first briefly address plaintiffs' motion for leave to file a second amended complaint. (Dkt. #52.) For reasons just explained, the court concluded that plaintiffs' operative complaint fails to state a claim upon which relief can be granted. Because plaintiffs' proposed, second amended complaint is substantively identical to its operative complaint -- the amended complaint simply names different defendants -- it is likewise deficient, and the court will accordingly deny plaintiffs' request for leave to file the second amended complaint on the grounds that it would be futile to do so. *Foman v. Davis*, 371 U.S. 178, 182 (1962) (court may deny opportunity to amend complaint based on futility of amendment); *Bethany Pharmacal Co. v. QVC, Inc.*, 241 F.3d 854, 861 (7th Cir. 2001) ("[D]istrict court need not allow an amendment when ... the amendment would be futile.").

ORDER

IT IS ORDERED that:

1) Defendants' motions to dismiss (dkts. #4, 6, 7, 10, 13) are GRANTED IN PART and DENIED IN PART consistent with the Opinion above.

2) Plaintiffs' motion for leave to file a second amended complaint (dkt. #52) is DENIED.

3) Consistent with this Opinion and Order, plaintiffs may have until May 15, 2020, to seek leave to file an amended complaint, if they so choose. Failure to do so will result in dismissal of this case without prejudice.

All Citations

Slip Copy, 2020 WL 1974190

Footnotes

1 In dismissing "Sunoco, Inc. (R & M)," plaintiffs wrote: "Sunoco (R&M), LLC (incorrectly named as Sunoco, Inc. (R&M)." (Pls.' Notice of Dismissal (dkt. #41) 1.) This led the clerk's office to create two Sunoco defendants in ECF. However, it is apparent from plaintiffs' filings and defendants' responses that the two Sunoco defendants are the same; the court therefore directs the clerk's office to delete Sunoco (R&M), LLC from CM/ECF.

2 For some unknown reason, this text order was not formally assigned a docket number, but can be found in the docket entries between dkt. ##42 & 43.

3 The *Beaver* lawsuit was temporarily removed to the Western District of Wisconsin, *see* No. 10-CV-375-WMC.

2016 WL 4217758
Only the Westlaw citation is currently available.
United States District Court, D. Minnesota.

IN RE: MIRAPEX PRODUCTS LIABILITY LITIGATION.
Kathryn Gillette et al., Plaintiffs,
v.
Boehringer Ingelheim Pharmaceuticals, Inc. et al., Defendants.

MDL No. 07-1836 (MJD/FLN)
|
Civil No. 15-cv-3005 (MJD/FLN)
|
Signed 06/16/2016

Attorneys and Law Firms

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ORDER AND REPORT AND RECOMMENDATION

FRANKLIN L. NOEL, United States Magistrate Judge

***1 THIS MATTER** came before the undersigned United States Magistrate Judge on the following motions: Defendant Boehringer Ingelheim Pharmaceuticals, Inc.'s ("BIPI") motion for summary judgment (ECF No. 56); Defendants Pfizer, Inc., Pharmacia Corp., and Pharmacia & Upjohn Co.'s (collectively, "Pfizer") motion for summary judgment (ECF No. 63); and Defendants' joint motion to strike Plaintiffs' sur-reply brief and exhibits (ECF No. 82). [1] The motions for summary judgment were referred to the undersigned for Report and Recommendation pursuant to 28 U.S.C. § 636 and Local Rule 72.1. Order, ECF No. 68. For the reasons set forth below, the Court recommends that both motions for summary judgment be **GRANTED**. Defendants' joint motion to strike Plaintiffs' sur-reply brief is **DENIED**.

I. FINDINGS OF FACT

A. Background

At all times relevant to the allegations in the Amended Complaint, Plaintiffs Kathryn Gillette and Raif Szczepanski were residents of Indianapolis, Indiana. Am. Compl. ¶ 1, ECF No. 42. Szczepanski is Gillette's spouse. *Id.*

1. Gillette's history of taking Mirapex

On June 15, 2001, Gillette presented to Leo T. d'Ambrosio, M.D., with symptoms of restless leg syndrome ("RLS"). Pls.' Ex. A, at 7, ECF No. 79-1. Gillette was prescribed the drug Mirapex at a dosage of 0.125 mg, two times per day. *Id.* By September 26, 2003, Gillette was taking Mirapex "three times per day without problems." *Id.* at 10.

Gillette had an appointment with Danica Vasilchek, M.D., on June 11, 2008, complaining of symptoms related to her RLS. Scott Aff. Ex. A, at 1–3, ECF No. 60. Dr. Vasilchek increased Gillette's dosage of Mirapex to one to three 0.5 mg tablets per day. *Id.* at 2. Gillette subsequently visited Dr. Vasilchek on April 16, 2010 for continued symptoms of RLS. ECF No. 60, Ex. B., at 1. Dr. Vasilchek again increased Gillette's dosage and instructed Gillette to take two to three 0.75 mg tablets (i.e., a daily dose of 1.5–2.25 mg) of Mirapex a few hours prior to her bedtime. *Id.* at 2.

Gillette's pharmacy records show that her April 16, 2010 prescription was filled with 1.5 mg tablets of Mirapex's generic equivalent—pramipexole dihydrochloride—not brand-name Mirapex. ECF No. 60, Ex. C, at 2. These tablets had a National Drug Code ("NDC") of 00555061514.[2] *Id.* According to FDA records, medications with this NDC were produced by Barr Laboratories, Inc., not BIPI or Pfizer. Sergretario Decl. ¶ 4, ECF No. 59. Gillette was provided with Barr Laboratories' pramipexole dihydrochloride on four other occasions—June 9, 2010, October 27, 2010, February 14, 2011, and March 29, 2011. ECF No. 60, Ex. C, at 18.

***2** Beginning in November 2011, Gillette's pharmacy began filling her Mirapex prescription with 0.75 mg tablets of pramipexole dihydrochloride manufactured by Teva Pharmaceuticals USA, Inc. (NDC #00093801998). *Id.* Gillette was provided with Teva Pharmaceuticals' tablets on at least ten separate occasions between November 4, 2011 and September 1, 2012. *Id.* Between October 2012 and November 2013, Gillette's pharmacy filled her Mirapex prescription with 0.75 mg tablets of pramipexole dihydrochloride manufactured by Torrent Pharmaceuticals Ltd. (NDC #13668018490). *Id.* Gillette was dispensed Torrent Pharmaceuticals' tablets on at least four occasions during this time frame. *Id.*, Ex. C, at 6, 18. Finally, beginning in November 2013, Gillette's pharmacy filled her Mirapex prescription with 0.5 mg tablets of pramipexole dihydrochloride (NDC #68462033290) manufactured by Glenmark Generics Inc. USA. *Id.*, Ex. C, at 18. Gillette was provided with Glenmark Generics' tablets on at least fifteen occasions, from December 23, 2013 until she stopped taking the drug in late 2015. *Id.*, Ex. C, at 18–19. The Court observes that there are no records of Gillette's pharmacy giving Gillette any tablets of Mirapex manufactured by BIPI and/or Pfizer after April 16, 2010.

2. Gillette's history of compulsive gambling

According to Plaintiffs' Amended Complaint, shortly after Gillette's daily dose of Mirapex was increased to 1.5–2.25 mg in 2010, Gillette began to gamble compulsively in casinos. ECF No. 42 ¶ 21. Plaintiffs state that "[o]ver the next three years, [Gillette] developed pathological gambling habits, which consumed her thoughts, actions and had a detrimental effect on her relations with her family, including her spouse." *Id.* ¶ 22. According to Plaintiffs, "[f]rom 2010 through July 2013, Plaintiff Gillette's pathological gambling resulted in significant financial losses for her and her spouse." *Id.* ¶ 23. This time frame was confirmed by Gillette in a "Fact Sheet" she completed under oath, wherein she stated, "In April 2010, my dosage of Mirapex increased and within a week of that increase my behavior started to change and I began to gamble compulsively." Smith Aff. Ex. A, at 3, ECF No. 85. Gillette alleges that such gambling caused her to suffer severe physical and economical damages.

Despite Gillette's numerous statements that her compulsive gambling did not start until after April 2010, she now alleges in her sur-reply memorandum,[3] for the first time, that her fascination with gambling in fact began in 2001, soon after she was originally prescribed Mirapex for her RLS. *See* Pls.' Sur-Reply Mem., ECF No. 74. For example, Gillette claims that she felt a deep desire to gamble while watching individuals play blackjack in a cruise-ship-casino in May 2004. *Id.* at 4. Acting on her desire to gamble, Gillette traveled to Europe in order to enter a casino in Monte Carlo. *Id.* Then, in 2007, Gillette purchased a deck of cards at Niagara Falls in order to play blackjack. *Id.* According to Gillette, her urges to gamble worsened after her dosage increase in April 2010.

B. Procedural history

Plaintiffs, appearing *pro se*, filed their original Complaint on June 11, 2015 in the U.S. District Court for the Southern District of Indiana. *See* Compl., ECF No. 1. On July 8, 2015, the U.S. Judicial Panel on Multidistrict Litigation ("JPML") entered a

conditional transfer order, transferring this action to the District of Minnesota as part of the multidistrict litigation ("MDL") *In re Mirapex Product Liability Litigation*, MDL No. 07-1836.

On July 31, 2015, Defendants filed a joint motion to dismiss Plaintiffs' Complaint. Mot. to Dismiss, ECF No. 19. Given the nature of Plaintiffs' claims, the undersigned referred Plaintiffs to the Federal Bar Association's *Pro Se* Project. Ltr., ECF No. 28. Pursuant to this referral, Plaintiffs retained the services of two volunteer attorneys, who agreed to assist Plaintiffs by filing an Amended Complaint and representing them in an early settlement conference with the Court. Plaintiffs' Amended Complaint alleges seven causes of action: (1) strict liability (design, manufacturing, and warning defects), (2) breach of express warranty, (3) breach of implied warranty, (4) negligence, (5) negligence per se, (6) negligent misrepresentation, and (7) loss of consortium. Am. Compl. ¶¶ 24–60, ECF No. 42. Due to the filing of Plaintiffs' Amended Complaint, Defendants withdrew their joint motion to dismiss.

***3** An early settlement conference with the undersigned was held on January 12, 2016. The parties, however, did not resolve the issues in this lawsuit. Following the settlement conference, the two volunteer attorneys representing Plaintiffs through the *Pro Se* Project withdrew, as the scope of their limited representation was complete. Mot. to Withdraw, ECF No. 48; Order, ECF No. 51.

During a teleconference with the Court on February 16, 2016, the parties agreed that Defendants should be allowed to move for summary judgment before adopting a discovery schedule. Sch. Order, ECF No. 55. Pursuant to that agreement, the Court issued a Scheduling Order, outlining the following briefing schedule: Defendants' motions for summary judgment were due by March 1, 2016, Plaintiffs' opposition memorandum was due by April 1, 2016, and Defendants' reply memoranda were due by April 15, 2016. *Id.*

Through their respective motions, Defendants argue that the prescription medication that allegedly caused Gillette's injuries was not manufactured by either BIPI or Pfizer, and therefore Defendants are not liable to Plaintiffs under Indiana law. Plaintiffs filed their opposition memorandum on March 28, 2016, and Defendants subsequently filed their reply memoranda on April 15, 2015. Opp'n Mem., ECF No. 77; BIPI's Reply, ECF No. 70; Pfizer's Reply, ECF No. 72. After briefing on Defendants' motions had closed, Plaintiffs filed an unauthorized sur-reply memorandum on April 25, 2016. ECF No. 74. In response, Defendants filed a joint motion to strike Plaintiffs' memorandum. Mot. to Strike, ECF No. 82. Plaintiffs oppose Defendants' motion.

II. STANDARD OF REVIEW

Summary judgment is proper if the evidence, viewed in the light most favorable to the nonmoving party, demonstrates that there are no genuine disputes of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Anderson v. Larson*, 327 F.3d 762, 767 (8th Cir. 2003). A disputed fact is material only if it might affect the outcome of the case under the governing substantive law, and a dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A party opposing a motion for summary judgment "may not rest upon the mere allegations or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial." *Khoury v. Grp. Health Plan, Inc.*, 615 F.3d 946, 952 (8th Cir. 2010).

III. CONCLUSIONS OF LAW

A. Plaintiffs' claims for strict liability, negligence, negligence per se, and negligent misrepresentation

1. The state law claims are preempted by the Indiana Products Liability Act

Plaintiffs' Amended Complaint asserts numerous state law causes of action, including: (1) strict liability (design, manufacturing, and warning defects), (2) negligence, (3) negligence per se, and (4) negligent misrepresentation. ECF No. 42 ¶¶ 24–58. When

a diversity action is transferred as part of an MDL, the MDL Court must apply the law of the transferor forum. *See In re Vioxx Prods. Liab. Litig.*, 478 F. Supp. 2d 897, 903 (E.D. La. 2007); *see also In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 489 F. Supp. 2d 932, 934–936 (D. Minn. 2007) (stating that when a diversity action is transferred as part of an MDL, the transferor court's choice-of-law rules continue to apply even if the complaint is later amended in the transferee court). Plaintiffs, who are Indiana residents, filed their original Complaint in the U.S. District Court for the Southern District of Indiana. *See* Compl., ECF No. 1. The action was thereafter transferred by the JPML as part of the Mirapex MDL. The Court therefore applies Indiana law to the present action.

***4** Defendants argue that Plaintiffs' claims are subject to, and governed by, the Indiana Products Liability Act ("IPLA"), Ind. Code § 34-20-1-1 *et seq.* ECF No. 58 at 5. Plaintiffs did not object to the application of the IPLA to their claims.

The first section of the IPLA states:

This article governs all actions that are:

(1) brought by a user or consumer;

(2) against a manufacturer or seller; and

(3) for physical harm caused by a product;

regardless of the substantive legal theory or theories upon which the action is brought.

Ind. Code § 34-20-1-1. The statute defines "consumer" as "any individual who uses or consumes the product." Ind. Code § 34-6-2-29. A "manufacturer" is defined as "a person or entity who designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product before the sale of the product to a user or consumer." *Id.* § 34-6-2-77. According to the Indiana Supreme Court, the legislature "clearly intended that the [IPLA] govern all product liability actions, whether the theory of liability is negligence or strict liability in tort." *Stegemoller v. ACandS, Inc.*, 767 N.E.2d 974, 975 (Ind. 2002). Courts have also held that the IPLA governs breach of warranty claims that are based in tort. *Hathaway v. Cintas Corp. Servs., Inc.*, 903 F. Supp. 2d 669, 672–73 (N.D. Ind. 2012).

Here, Plaintiffs contend that Gillette, a consumer, purchased and used the product Mirapex, a prescription drug that is jointly manufactured by Defendants. *See* ECF No. 42 ¶ 9. Given the IPLA's express language, as well as the holdings of various courts in Indiana, it is clear to the Court that Plaintiffs' common law claims for strict liability, negligence, negligence per se, and negligent misrepresentation are all preempted by the IPLA. The Court therefore construes these claims as one single cause of action under the IPLA. *See Ryan ex rel. Estate of Ryan v. Philip Morris USA, Inc.*, No. 1:05-cv-162, 2006 WL 449207 (N.D. Ind. Feb. 22, 2006) (dismissing plaintiff's common law claims for negligence and fraud, but allowing plaintiff's allegations to proceed under the IPLA).

2. Defendants' product did not proximately cause Plaintiffs' alleged injuries

The IPLA provides:

[A] person who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to the user's or consumer's property is subject to liability for physical harm *caused by that product* to the user or consumer or to the user's or consumer's property if:

(1) that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;

(2) the seller is engaged in the business of selling the product; and

(3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable under this article.

Ind. Code § 34-20-2-1 (emphasis added). The statute makes clear that in order to avoid summary judgment, Plaintiffs must be able to set forth specific facts showing that Defendants' sold, leased, or otherwise put into the stream of commerce the prescription drug that proximately caused Gillette physical harm. *See Thornburg v. Stryker Corp.*, No. 1:05-cv-1378-RLY-TAB, 2006 WL 1843351, at *3–4 (S.D. Ind. June 29, 2006) (holding that the plaintiff did not raise a triable issue of fact that the defendant sold or manufactured the injury-causing product); *Piltch v. Ford Motor Co.*, 11 F. Supp. 3d 884, 888 (N.D. Ind. 2014) (stating that the IPLA requires proof that the defendant's product proximately caused the plaintiff's injuries). Proximate cause requires, at a minimum, causation in fact—that is, that the harm would not have occurred "but for" the defendants' conduct. *Daub v. Daub*, 629 N.E.2d 873, 877 (Ind. Ct. App. 1994). Although proximate cause is generally a question of fact, it becomes a question of law where only a single conclusion can be drawn from the facts. *Florio v. Tilley*, 875 N.E.2d 253, 256 (Ind. Ct. App. 2007).

a. The relevant time period for causation

***5** Gillette has not alleged that she suffered any injury until after April 16, 2010. For nine years, while on a dosage of 0.50 mg or lower of Mirapex, Gillette did not exhibit any symptoms of compulsive gambling. Indeed, Plaintiffs state in their Amended Complaint that it was not until after Gillette's dosage of Mirapex was increased to at least 1.5 mg in 2010 that she began to develop pathological gambling habits. ECF No. 42 ¶¶ 21–22; *see also id.* ¶ 23 ("From 2010 through July 2013, Plaintiff Gillette's pathological gambling resulted in significant financial losses for her and her spouse."). In her "Fact Sheet," Gillette stated, under oath, that she did not begin to gamble compulsively until after her dosage of Mirapex was increased in April 2010. ECF No. 85, Ex. A, at 2, 3. Apart from including a few self-serving statements in her sur-reply memorandum regarding *isolated* instances of gambling between 2001 and 2010, Gillette has put forth no evidence that she suffered from any symptoms of *compulsive* gambling until after the increase in her dosage of Mirapex on April 16, 2010. *See Frevert v. Ford Motor Co.*, 614 F.3d 466, 473–74 (8th Cir. 2010) ("[A] properly supported motion for summary judgment is not defeated by self-serving affidavits. Rather, the plaintiff must substantiate allegations with sufficient probative evidence that would permit a finding in the plaintiff's favor." (internal citations omitted)). She has also provided no expert opinions that her compulsive gambling was caused by any prescription drug taken prior to her April 2010 dosage increase. *See Piltch v. Ford Motor Co.*, 778 F.3d 628, 632 (7th Cir. 2015) (stating that under the IPLA, expert testimony on an issue is required when the issue is not within the understanding of a lay person). The Court therefore concludes that Gillette's injures at issue in this lawsuit could only have been caused by prescription medication that Gillette ingested after April 16, 2010.

b. Gillette only ingested Mirapex's generic equivalent during the relevant time period

Plaintiffs have failed to present any specific facts that suggest Gillette's injuries caused by prescription drugs manufactured by Defendants. As discussed above, Gillette's pharmacy records indicate that all of the tablets dispensed to Gillette after April 16, 2010 pursuant to her prescription for Mirapex were various forms of Mirapex's generic equivalent, pramipexole dihydrochloride, and not brand-name Mirapex. These tablets were manufactured by pharmaceutical companies separate and apart from Defendants. *See* ECF No. 60, Ex. C. In other words, at no time during the relevant time period where Gillette was exhibiting symptoms of compulsive gambling was she ingesting a product manufactured by BIPI or Pfizer. Plaintiffs cannot, therefore, show that Defendants manufactured, sold, or otherwise put into the stream of commerce a product that proximately caused Gillette to gamble compulsively. [4] *See* Ind. Code § 34-20-2-1.

In addition, manufacturers of a brand-name product are generally not liable for injuries caused to users of a generic equivalent (i.e., "innovator liability"). Although the Indiana Supreme Court has not directly addressed this issue, it is clear that the vast

majority of courts throughout the country have rejected claims of innovator liability. *See, e.g.*, *Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013) (holding that plaintiff could not hold brand-defendants liable for injuries caused from ingesting a generic product); *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014) (observing that an overwhelming majority of courts have rejected innovator liability); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013) (finding that the "overwhelming national consensus" is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product). In the absence of controlling precedent by Indiana's highest court, the Court "must attempt to predict how the highest court would resolve the issue." *Campbell v. Davol, Inc.*, 620 F.3d 887, 894 (8th Cir. 2010). However, "[i]t is not the role of a federal court to expand state law in ways not foreshadowed by state precedent." *Ashley Cty. v. Pfizer, Inc.*, 552 F.3d 659, 673 (8th Cir. 2009).

The plain language of the IPLA does not support a theory of innovator liability in Indiana. The opening clause of § 34-20-2-1 requires that the defendant must have sold, leased, or otherwise put into the stream of commerce the product that caused the user or consumer's physical harm. Defendants cannot be held liable under the IPLA because they did not sell, lease, or put the generic drug into commerce. In addition, the court in *Stewart v. Sanofi Aventis U.S., LLC*, interpreting Indiana law, rejected a theory of innovator liability and held that the manufacturer of a brand-name drug could not be held liable for injuries sustained from ingesting a generic equivalent. 15 F. Supp. 3d 1151 (N.D. Ala. 2014) (relying on *Short v. Eli Lilly & Co.*, No. 49D 12-0601-CT-2187 (Ind. Super. Ct. Mar. 25, 2009)); *see also In re Darvocet*, 756 F.3d at 945 (predicting that the Indiana Supreme Court would decline to recognize that brand manufacturers owe generic customers a duty of care that could give rise to liability). Based on the overwhelming authority that has declined to recognize a theory of innovator liability, the Court agrees with the *Stewart* and *In re Darvocet* courts that the Indiana Supreme Court would decline to recognize a theory of innovator liability. Plaintiffs cannot hold Defendants liable for generic drugs manufactured by different pharmaceutical companies.

***6** The Court recognizes, however, that its decision leaves Plaintiffs with little recourse for the alleged harms caused by ingesting generic pramipexole dihydrochloride. Indeed, the Supreme Court has held that state tort claims against a generic drug manufacturer for failing to provide adequate warning labels are preempted by federal law. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624–27 (2011) (acknowledging the difficult position federal drug laws place plaintiffs suing generic drug manufacturers). However, "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." *Id.* at 625. Summary judgment must be entered in favor of Defendants.

B. Plaintiffs' breach of warranties claims

The IPLA governs breach of warranty claims that are based in tort. *Hathaway v. Cintas Corp. Servs., Inc.*, 903 F. Supp. 2d 669, 672–73 (N.D. Ind. 2012). It is unclear by Plaintiffs' Amended Complaint whether their claims for breach of express and implied warranties are based in contract or tort. Plaintiffs, however, do not dispute Defendants' contention that all of their causes of action, including those for breach of express and implied warranties, are governed by the IPLA. Therefore, to the extent Plaintiffs' breach of warranties claims are based in tort, the Court concludes that summary judgment is warranted in favor of Defendants because such claims have been subsumed by the IPLA. *See id.* at 673 (entering summary judgment in favor of defendants on plaintiffs breach of warranties claims based in tort because such claims merged into plaintiffs' IPLA claim). [5]

C. Plaintiff Szczepanski's claim for loss of consortium

Gillette's husband, Szczepanski, brings a claim for loss of consortium against Defendants. ECF No. 42 ¶¶ 59–60. A loss of consortium claim, however, is derivative in nature because it "derives its viability from the validity of the claim of the injured spouse against the wrongdoer." *Nelson v. Denkins*, 598 N.E.2d 558, 563 (Ind. Ct. App. 1992). "[A] loss of consortium claim cannot be brought when the injured spouse's claim has been adjudicated and lost." *Bender v. Peay*, 433 N.E.2d 788, 792 (Ind. Ct. App. 1982). Because Plaintiffs' product liability claims against Defendants for injuries suffered by Gillette are not actionable, summary judgment must be entered in favor of Defendants on Szczepanski's claim for loss of consortium. *See id.* at 791 ("Since a loss of consortium claim derives its viability from the injured spouse's claim for injuries, we fail totally to understand how a defendant could be liable to one spouse on a loss of consortium claim when it has already been determined [that the defendant] did not cause the other spouse's injuries.").

IV. ORDER

***7** Based upon the foregoing, and all of the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Defendants' joint motion to strike Plaintiffs' sur-reply brief (ECF No. 82 (Case No. 15-cv-3005); ECF No. 1977 (Case No. 07-md-1836)) is **DENIED**.

V. RECOMMENDATION

Based upon the foregoing, and all of the files, records, and proceedings herein, **IT IS HEREBY RECOMMENDED** that:

A. BIPI's motion for summary judgment (ECF No. 56 (Case No. 15-cv-3005); ECF No. 1960 (Case No. 07-md-1836)) be **GRANTED**;

B. Pfizer's motion for summary judgment (ECF No. 63 (Case No. 15-cv-3005); ECF No. 1968 (Case No. 07-md-1836)) be **GRANTED**.

All Citations

Not Reported in Fed. Supp., 2016 WL 4217758

Footnotes

1 This action is a member of the multidistrict litigation *In Re: Mirapex Products Liability Litigation*, Case No. 07-md-1836 (MJD/FLN). Defendants' motions and supporting memoranda in the present action were also filed in the Mirapex MDL. *See* BIPI's Mot. for Summ. J., ECF No. 1960; Pfizer's Mot. for Summ. J., ECF No. 1968; Defs.' Mot. to Strike, ECF No. 1977.

2 According to James Segretario, BIPI's Director of Regulatory Affairs, every prescription drug product approved by the FDA for distribution in the United States, whether brand-name or generic, contains a unique identification number, known as the NDC. ECF No. 59 ¶ 2. One may use the NDC to look up the manufacturer of a prescription drug through the FDA's website. *Id.* (citing http://www.fda.gov/drugs/InformationOnDrugs/ucm142438.htm).

3 Defendants have filed a joint motion to strike this memorandum as it was filed in violation of LR 7.1 and in contravention of the Court's Scheduling Order. Mot. to Strike, ECF No. 82. While the Court acknowledges that Plaintiffs' sur-reply is procedurally improper, the Court nevertheless declines to strike the memorandum and its accompanying exhibits because they do not materially impact the Court's decision. Defendants' joint motion to strike is denied.

4 Pfizer is even further removed from the line of causation as it no longer sold Mirapex or maintained any control over the Mirapex New Drug Application after January 1, 2005. Divan Decl. ¶ 3, ECF No. 65. According to Pfizer, it did not manufacture, sell, or place into commerce any brand-name Mirapex after that date. *Id.*

5 Although not addressed by either party, the Court observes that to the extent Plaintiffs' breach of warranties claims are based in contract, summary judgment must be entered in favor of Defendants because Defendants drug did not proximately cause Gillette's injuries. “Any action based on breach of warranty requires evidence showing not only the existence of the warranty but that the warranty was broken and that the breach of warranty was the proximate cause of the loss sustained.” *Frantz v. Cantrell*, 711 N.E.2d 856, 860 (Ind. Ct. App. 1999). As discussed above, at the time Gillette was taking brand-name Mirapex, Gillette did not suffer from any episodes of compulsive gambling. It was not until Gillette began taking generic pramipexole dihydrochloride, manufactured by entities separate from Defendants, did

Gillette began to gamble compulsively. There is nothing in the record to suggest that Defendants' brand-name Mirapex proximately caused Gillette's injuries. Summary judgment must be entered in favor of Defendants on Plaintiffs' claims for breach of express and implied warranties.

End of Document

2016 WL 4203422
Only the Westlaw citation is currently available.
United States District Court, D. Minnesota.

IN RE: MIRAPEX PRODUCTS LIABILITY LITIGATION
This document relates to: Kathryn GILLETTE, et al., Plaintiffs,
v.
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., et al., Defendants.

MDL File No. 07–1836 (MJD/FLN)
|
Civil File No. 15–3005 (MJD/FLN)
|
Signed August 8, 2016
|
Filed 08/09/2016

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ORDER

Michael J. Davis United States District Court

***1** The above-entitled matter comes before the Court upon the Report and Recommendation of United States Magistrate Judge Franklin L. Noel dated June 16, 2016. Plaintiffs filed objections to the Report and Recommendation.

Pursuant to statute, the Court has conducted a de novo review upon the record. 28 U.S.C. § 636(b)(1); Local Rule 72.2(b). Based upon that review, the Court **ADOPTS** the Report and Recommendation of United States Magistrate Judge Noel dated June 16, 2016.

Accordingly, based upon the files, records, and proceedings herein, **IT IS HEREBY ORDERED**:

1. The Court **ADOPTS** the Report and Recommendation of United States Magistrate Judge Franklin L. Noel dated June 16, 2016 [Docket No. 90 (Case No. 15–cv–3005)] [Docket No. 1984 (Case No. 07–md–1836)].

2. Defendant Boehringer Ingelheim Pharmaceuticals, Inc.'s Motion for Summary Judgment [Docket No. 56 (Case No. 15–cv–3005)] [Docket No. 1960 (Case No. 07–md–1836)] is **GRANTED**.

3. Defendants Pfizer Inc., Pharmacia Corporation and Pharmacia & Upjohn LLC's Motion for Summary Judgment [Docket No. 63 (Case No. 15–cv–3005)] [Docket No. 1968 (Case No. 07–md–1836)] is **GRANTED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

All Citations

Not Reported in Fed. Supp., 2016 WL 4203422

2009 WL 9867531 (Ind.Super.) (Trial Order)
Superior Court of Indiana.
Civil Division
Marion County

Kimberly K. SHORT, Individually and as Special Administratrix
of the Estate of James K. Short, deceased, Plaintiff,
v.
ELI LILLY AND COMPANY, Smithkline Beecham Corporation d/b/a Glaxosmithkline, PAR Pharmaceutical Companies, Inc., Anonymous Physician, and Anonymous Hospital, Defendants.

Nos. 49D12-0601-CT-2187, 4:13-cv-00539-VEH.
March 25, 2009.

Findings of Fact, Conclusions of Law and Order on Eli Lilly and Company's Motion for Summary Judgment

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***1** This matter came before the Court for hearing on February 3, 2009, on Defendant Eli Lilly and Company's ("Lilly") motion for summary judgment on Plaintiff's Prozac(r)-related claims. Plaintiff appeared by counsel Kathy A. Lee. Lilly appeared by counsel Christopher P. Gramling and Jan M. Carroll.

Plaintiff alleges that her husband, Dr. James Short, committed suicide after being treated with Lilly's prescription antidepressant Prozac(r) and other prescription medications. In its brief and designation of evidence on its motion for summary judgment ("Lilly's Motion"), Lilly set forth evidence negating essential elements of Plaintiff's claims and establishing that James Short did not ingest brand-name Prozac(r) manufactured by Lilly, but rather that he used only generic fluoxetine provided by Par Pharmaceutical and Barr Pharmaceuticals Inc. Plaintiff failed to timely file response to the motion for summary judgment. In addition, at the hearing on Lilly's Motion, Plaintiff's counsel conceded she has no evidence that James Short used Prozac(r) manufactured by Lilly. The Court having considered Lilly's Motion, brief and designation of evidence, and the parties' arguments, and otherwise being duly advised, the Court hereby grants Lilly's summary judgment motion and ENTERS the

following Findings of Fact, Conclusions of Law and Order for judgment in favor of Lilly and against Plaintiff on her Prozac(r)-related claims.

FINDINGS OF UNCONTESTED FACT

1. Plaintiff has not timely designated any disputed issues of material fact and has not contested any of the facts designated by Lilly in support of its summary judgment motion.

2. This case arises out of the suicide of Dr. James Short. Dr. Short, a local physician who had been diagnosed with depression and bipolar disorder, committed suicide on January 26, 2004, by a self-inflicted gunshot wound. *See* Plaintiffs Complaint for Damages, ¶¶ 19, 22-32, and 43.

3. Following his suicide, his widow, Kimberly Short, brought this action asserting professional malpractice claims against a physician and a hospital that treated James Short, and asserting product liability claims against several pharmaceutical companies that were alleged to have manufactured various FDA-approved prescription medications that he allegedly had been taking. Plaintiff brought claims against Lilly based on James Short's alleged use of Prozac(r) and Zyprexa(r). *See* Plaintiff's Complaint for Damages.

4. Prozac(r) is Lilly's brand name for the drag fluoxetine. *See* Eli Lilly and Company's Responses to Plaintiff's First Set of Interrogatories Responses Nos. 4, 5, and 6, attached as Exhibit 2 to Lilly's Motion.

5. The undisputed evidence designated by Lilly establishes James Short did not use brand-name Prozac(r) manufactured by Lilly and that he used only generic fluoxetine that was supplied by companies other than Lilly.

6. James Short was first prescribed fluoxetine on November 5, 2003, by Dr. Goddard. *See* Goddard Medical Record dated 11/5/03.

7. This prescription was filled on November 6, 2003, with generic fluoxetine manufactured by Barr Pharmaceuticals Inc. *See* Deposition of Kimberly Short ("Short Dep."), at 307:20-24; 375:2-14.

***2** 8. Decedent's prescription for fluoxetine was renewed by Anonymous Physician on December 22, 2003. *See* Anonymous Hospital Record dated 12/22/03, attached as Exhibit 6 to Lilly's Motion.

9. This renewed prescription was filled on December 22, 2003, with generic fluoxetine manufactured by Par Pharmaceutical. *See* CVS Pharmacy Record dated 12/22/03; Short Dep. at 307:15-308:1; 388:15-389:2.

10. Decedent's prescription for fluoxetine was again renewed by Anonymous Physician on January 13, 2004. *See* Anonymous Hospital Record dated 1/13/04. That prescription for fluoxetine was never filled. *See* Short Dep., at 308:22-309:8; 391:4-17.

11. Decedent committed suicide on January 26, 2004, without having received any further prescriptions for fluoxetine and without having ingested brand-name Prozac(r) manufactured by Lilly.

12. James Short did not have any conversations with, or receive any statements from, any representative of Lilly about Prozac(r) prior to or in connection with his prescription for fluoxetine. *See* Short Dep., at 373:4-7; 410:18-25; 412:1-6.

13. On May 17, 2007, Lilly and Defendants Par Pharmaceutical, Inc., and GlaxoSmithKline filed their motion to stay the action during the pendency of the proceedings before the Medical Review Panel on Plaintiff's claim against Anonymous Physician and Anonymous Hospital. On May 25, 2007, Plaintiff filed her response to the motion for stay, and asked the Court to "stay this matter against Defendants" until the malpractice action was resolved before the Department of Insurance "with the exception that

discovery in this Lawsuit be carried on against Defendants." The Court. entered the stay Order, adopting Plaintiffs language that the matter be stayed against Defendants except for discovery. Nothing in the Order precluded the Defendants from proceeding with any aspect of this case.

14. On July 2, 2007, when the attorneys appeared before Judge Gary Miller he clarified that the stay applies to the Court setting any discovery cut-off dates until further advised and that discovery against the defendants is to proceed.

15. Lilly filed its motion for summary judgment on October 14, 2008. Pursuant to Trial Rule 56, Plaintiff's response to Lilly's Motion was due November 13, 2008.

16. On October 31, 2008, Plaintiff filed an unopposed request for a 45-day enlargement of time to respond to Lilly's Motion.

17. The Court granted this request and extended Plaintiff's response deadline from November 13, 2008, to December 29, 2008.

18. On November 3, 2008, the Court scheduled a hearing on Lilly's Motion for December 15, 2008.

19. On December 9, 2008, Plaintiff filed an unopposed request to continue the hearing scheduled for December 15, 2008.

20. On December 12, 2008, the Court granted Plaintiff's request and rescheduled the hearing for February 3, 2009.

21. Plaintiff did not file any response or designate any evidence in response to Lilly's Motion by the December 29, 2008, deadline.

22. Plaintiff did not file any response or designate any evidence in response to Lilly's Motion prior to the February 3, 2009, hearing on Lilly's Motion.

23. At the February 3, 2009, hearing, Plaintiff sought leave to submit portions of Anonymous Physician's deposition testimony as evidence in opposition to Lilly's Motion.

***3** 24. Plaintiff conceded at the February 3, 2009, hearing that she did not have any evidence that James Short used brand-name Prozac(r) manufactured by Lilly.

CONCLUSIONS OF LAW

Summary Judgment Standard

1. "The purpose of summary judgment is to terminate litigation when there is no factual dispute and the moving party is entitled to judgment as a matter of law." *Bushong v. Williamson*, 790 N.E.2d 467, 474 (Ind. 2003) (quoting *Kottlowski* v. *Bridgestone/Firestone, Inc.*, 670 N.E.2d 78, 82 (Ind. Ct. App. 1996), *transfer denied*. A defendant should not be forced to bear the expense and risk of trial in "defense of a claim which is supported solely by speculation or mere possibility." *Brannon v. Wilson*, 733 N.E.2d 1000, 1001-02 (Ind. Ct. App. 2000), *trans. denied*.

2. Under Indiana law, a defendant is entitled to summary judgment when it demonstrates that the undisputed facts negate at least one element of the plaintiff's claim. *Anderson v. Four Seasons Equestrian Center*, 852 N.E. 2d 576, 580 (Ind. Ct. App. 2006) (affirming summary judgment for defendant), *trans, denied*, 860 N.E.2d 599 (Ind. 2006).

3. A products liability defendant is entitled to summary judgment if the plaintiff fails to designate evidence on a necessary element of the plaintiff's case, such as the identity of the manufacturer of the product to which the plaintiff was exposed and a causal relationship between the plaintiff's injury and the defendant's product. *See Asbestos Corp. v. Akaiwa*, 872 N.E. 2d 1095,

1098 (Ind. Ct. App. 2007) (granting summary judgment for defendant where plaintiff "presented no evidence to establish a genuine issue of material fact as to whether he was exposed to or inhaled asbestos dust from the [manufacturer's] products ...").

4. A plaintiff cannot establish liability based on speculation or conjecture. *Hayden v. Paragon Steakhouse*, 731 N.E.2d 456, 458 (Ind. Ct. App. 2000) ("an inference is not reasonable and cannot create a genuine issue when it rests on no more than speculation and conjecture").

Failure to File a Respond to Summary Judgment Motion

5. Under Indiana law, when a nonmovant fails to respond to a motion for summary judgment before the response deadline, by either filing a response, requesting a continuance under Trial Rule 56(1), or filing an affidavit under Trial Rule 56(F), the trial court cannot consider the nonmovant's filings after the stipulated deadline. *See HomEq Servicing Corp. v. Baker*, 883 N.E.2d 95, 98-99 (Ind. 2008).

6. A party may not wait until the summary judgment hearing to oppose the motion. *Seufert v. RWB Med. Income Properties I Ltd. P'ship*, 649 N.E.2d 1070, 1073 (Ind. Ct. App. 1995).

7. If the non-moving party fails to properly respond or designate evidence before the response deadline as required by T.R. 56, and the moving party has shown that it is entitled to summary judgment, summary judgment must be entered against the non-moving party. *Morton v. Moss*, 694 N.E.2d 1148, 1152 (Ind. App. Ct. 1998).

8. The Plaintiff failed to timely file any response or designate any evidence in opposition to Lilly's Motion before the December 29, 2008, deadline.

9. Plaintiff attempted to oppose Lilly's motion for the first time at the February 3, 2009, hearing when she sought leave to submit excerpts from the deposition testimony of Anonymous Physician as evidence.

***4** 10. Under Indiana law, the Court lacks discretion to consider Plaintiff's untimely designation of evidence in response to Lilly's Motion. See *HomEq Servicing Corp. v. Baker*, 883 N.E.2d 95, 98-99 (Ind. 2008) (stating that the "bright line" rule in Indiana is that trial courts lack discretion to permit a nonmovant who has not responded before the response deadline to thereafter designate evidence); see *also Thayer v. Gohil*, 740 N.E.2d 1266, 1268 (Ind. Ct. App. 2001) (holding that where there has been no timely response or designation of materials in opposition to a summary judgment motion, the trial court has no discretion to consider untimely-filed materials), *trans, denied*.

11. Plaintiffs counsel attempted to explain Plaintiffs failure to timely respond to Lilly's Motion by stating that she thought the case was stayed. As noted above, the stay Order does not prevent any Defendant from filing a motion for summary judgment. Such a claim is also not consistent with Plaintiff's request for an extension of time to respond to Lilly's Motion and subsequent request for a continuance of the hearing on Lilly's Motion.

12. In addition, under Indiana law a party may not rely on a stay when that party is on notice of a summary judgment hearing date. *Brown v. Banta*, 682 N.E.2d 582, 585 (Ind. Ct. App.1997). A court's act of setting a hearing operates as a lifting of the stay with respect to the issue briefed in that motion. *Id.*

13. In this case, Plaintiff was put on notice by the Court's December 12, 2008; Order that the summary judgment hearing was scheduled for February 3, 2009. In fact, Plaintiff had asked the Court to reschedule the hearing.

14. Plaintiff's attempt to designate evidence in opposition to Lilly's summary judgment motion at the February 3, 2009, hearing is not timely. *Seufert* at 1073 (Ind. Ct. App. 1995) (nonmovant must offer evidence in opposition before the summary judgment hearing). Accordingly, the Court strikes Plaintiff's proffered evidence and will not consider it in ruling on Lilly's Motion. *Id.*

15. Because Plaintiff failed to respond to Lilly's motion, or to designate evidence in a timely fashion as required by Trial Rule 56, Lilly is entitled to summary judgment on all of Plaintiff's Prozac(r)-related claims. *See Brown v. Banta*, 682 N.E.2d 582, 585 (Ind. Ct. App. 1997) (affirming summary judgment for defendant where plaintiff failed to offer a timely response).

16. The Court accepts, and bases its Conclusions of Law on the uncontested material facts set forth by Lilly.

Lilly Is Entitled to Summary Judgment on All of Plaintiffs Prozac(r)-Related Claims Because James Short Did Not Use Prozac(r) Manufactured by Lilly

17. While Plaintiffs failure to respond to Lilly's motion is sufficient to warrant granting Lilly's Motion for summary judgment, the Court also concludes that Lilly's Motion should be granted because it is undisputed that James Short did not use brand-name Prozac(r) manufactured by Lilly.

18. Plaintiffs Prozac(r)-related claims against Lilly are all based on the allegation that James Short used Prozac(r) manufactured by Lilly.

19. The Indiana Products Liability Act ("IPLA") "governs all actions that are (1) brought by a user or consumer; (2) against a manufacturer or seller; ... (3) for physical harm caused by a product *regardless of the substantive legal theory or theories upon which the action is brought."* Ind. Code § 34-20-1-1 et seq. (2008) (emphasis added); *see also U-Haul Int'l, Inc. v. Nulls Machine & Mfg. Shop, 736* N.E.2d 271, 281 (Ind. Ct. App. 2000) (holding that the IPLA subsumes negligence and strict liability claims in personal injury cases); *Ryan v. Philip Morris*, 2006 WL 449207, *2 (N.D. Ind. Feb. 22, 2006) (finding plaintiff's common law negligence and fraud claims barred by the IPLA).

***5** 20. Plaintiff alleges that James Short's use of Prozac(r) manufactured by Lilly caused him to commit suicide. Her substantive theories for recovery - strict liability, negligence, and misrepresentation - all seek recovery for physical harm allegedly caused by a product.

21. Accordingly, all of Plaintiff's claims against Lilly are governed by the IPLA.

22. The IPLA expressly limits liability to manufacturers or sellers of the alleged injury-causing product. Ind. Code § 34-20-2-2 et seq.; *see also* Ind. Code § 34-6-2-115 (defining a "product liability action" for purposes of Indiana Code § 34-20, as an action that is "brought against a manufacturer or seller of a product" and is "for or on account of physical harm").

23. Under the IPLA, a "manufacturer" is defined as a "person or entity who designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product before the sale of the product to a user or consumer." Ind. Code § 34-6-2-77 (2008).

24. Under the IPLA, a "seller" is defined as a "person engaged in the business of selling or leasing a product for resale, use, or consumption." Ind. Code § 34-6-2-136 (2008).

25. In a products liability action under Indiana law, whether based on strict liability or negligence, the plaintiff must identify the manufacturer of the product and demonstrate a causal relationship between the injury and the manufacturer's product. *See Asbestos Corp. v. Akaiwa*, 872 N.E. 2d 1095, 1098 (Ind. Ct. App. 2007) (granting summary judgment for defendant because plaintiff presented no evidence to establish a genuine issue of material fact as to his exposure to any product made by defendant); *see also U-Haul Int'l Inc. v. Nulls Machine & Mfg. Shop*, 736 N.E.2d 271, 281 (Ind. Ct. App. 2000) (holding that a causal link between plaintiff's injury and defendant's product is "an essential element not only of a claim of strict liability, but also a claim sounding in negligence" and affirming summary judgment because plaintiff "failed to demonstrate a material issue of fact on the question of proximate cause.").

26. Lilly has designated evidence establishing that it did not manufacture or sell the generic brand fluoxetine used by James Short. Thus, it negates an essential element of Plaintiff's Prozac(r)-related claims. The undisputed evidence shows that the fluoxetine James Short allegedly used was provided by Par Pharmaceutical and Barr Pharmaceuticals Inc.

27. Accordingly, Lilly is not a "manufacturer" or "seller" as those terms are defined by the IPLA and, therefore, Lilly is not liable to Plaintiff under the IPLA.

28. Since the IPLA "provides the sole and exclusive remedy for personal injuries allegedly caused by a product" in Indiana, Lilly is entitled to summary judgment on all of Plaintiff's claims against Lilly related to Prozac(r). *Stegemoller v. AC and S, Inc.* 767 N.E.2d 974, 976 (Ind. 2002).

Lilly is Entitled to Summary Judgment on Plaintiff's Misrepresentation Claim Because James Short Did Not Receive or Rely on Any Statement from Lilly

29. The Plaintiff's misrepresentation claims are also governed by the IPLA. Thus, Lilly is entitled to judgment on this claim as well because James Short did not use Prozac(r) manufactured by Lilly. Lilly is also entitled to summary judgment on that claim because James Short did not receive or rely on any statement from Lilly.

***6** 30. Under Indiana law, a claim for intentional misrepresentation consists of the following elements: (1) the defendant made a material misrepresentation of a past or existing fact, (2) the material misrepresentation was false, (3) the misrepresentation was made with knowledge or reckless ignorance of the falsity, (4) the plaintiff relied upon the misrepresentation; and (5) that reliance proximately caused plaintiff's injury. *Eve v. Sandoz Pharm. Corp.*, 2001 U.S. Dist. LEXIS 4531, 85-88 (S.D. Ind. Mar. 7, 2001).

31. In Indiana, a plaintiff is entitled to rely only on a defendant's statement or representation that was directed to the plaintiff. *Id.* (granting summary judgment for defendant on fraud claim and holding that "since plaintiffs have not demonstrated that [defendants] made any misrepresentations to them personally, their fraud claim fails") (citations omitted); *see also Bilimoria Computer Sys., LLC v. Am. Online, Inc.*, 829 N.E.2d 150, 155 (Ind. Ct. App. 2005) (affirming summary judgment for defendant on fraud claim because defendant had demonstrated that it had no contact with, and made no representations to, plaintiff).

32. James Short did not have any conversations with, or receive any statements from, any representative of Lilly about Prozac(r) prior to or in connection with his prescription for generic fluoxetine. *See* Short Dep. at 373:4-7; 410:18-25; 412:1-6.

33. Accordingly, there was no statement by Lilly regarding Prozac(r) manufactured by Lilly or fluoxetine manufactured and sold by other entities that James Short received or relied on. In the absence of any such statement and reliance, Plaintiff's misrepresentation claim fails as a matter of law. *See, e.g., Bilimoria Computer Sys.*, 829 N.E.2d at 155 ("AOL did not make a representation to Bilimoria upon which Bilimoria was entitled to rely.").

34. Since James Short did not have any conversations with, or receive any statements from, any representative of Lilly about Prozac(r) prior to or in connection with his prescription for generic fluoxetine, there is no reliance on any statement from Lilly. *Id.*

35. Accordingly, under Indiana law, Plaintiff's misrepresentation claim fails as a matter of law because James Short did not receive or rely on any statement from Lilly. *Parks v. Danek Med., Inc.* 1999 WL 1129706 at *8 (N.D. Ind., 1999) (a plaintiff "must show *personal* reliance on an alleged concealment or misrepresentation to assert a fraud claim.") (emphasis in original).

The Original Designer Theory of Liability Adopted by the California Court Of Appeals in *Conte v.iWyeth* Is Inconsistent with Indiana Law

36. Under binding Indiana law, Lilly is entitled to summary judgment. The Court will address Plaintiffs argument at the February 3, 2009, hearing that an "original designer" theory of liability that was adopted by the California Court of Appeals in *Conte v Wyeth Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008), could impose a duty on Lilly in this case.

37. In *Conte*, the California Court of Appeals allowed a plaintiff to pursue negligent misrepresentation claims against a brand-name pharmaceutical manufacturer despite the fact that the plaintiff had not used that manufacturer's product but had instead used a generic equivalent manufactured by another entity.

38. Despite the clear requirements for product liability claims under Indiana law, Plaintiff urged this Court for the first time at the summary judgment hearing to hold that the Prozac(r)-related claims against Lilly are not precluded even though James Short did not use Prozac(r) manufactured by Lilly.

***7** 39. This Court declines Plaintiff's invitation to deviate from well-settled principles of Indiana law and adopt *Conte's* "original designer" theory of liability. *Conte* is fundamentally inconsistent with well-settled Indiana law and the most basic tenets of products liability law. *Conte* is also contrary to the overwhelming weight of authority which has unanimously rejected such an expansive theory of liability.

Conte Is Inconsistent With Indiana Law

40. This case, which was filed in Indiana by an Indiana plaintiff based on events that happened in Indiana, is governed by Indiana law. No party has argued that the Court should apply any law other than Indiana law.

41. *Conte* was based on the California Court of Appeals' interpretation of California common law.

42. Indiana law differs from California law in important and material ways that require the rejection of *Conte's* holding in a case governed by Indiana law.

43. One major difference between Indiana and California law is the source from which product liability claims are derived in each state.

44. Plaintiff's Complaint includes claims for strict liability, negligence, and misrepresentation. [1] Regardless of the labels Plaintiff uses, all of her claims seek recovery for physical harm allegedly caused by a product and, therefore, are all governed by the IPLA. Ind. Code § 34-20-1-1 et seq. (2008) (emphasis added); *see also U-Haul Int'l, Inc. v. Nulls Machine & Mfg. Shop*, 736 N.E.2d 271, 281 (Ind. Ct. App. 2000) (holding that the IPLA subsumes negligence and strict liability claims in personal injury cases); *Ryan v. Philip Morris*, 2006 WL 449207, *2 (N.D. Ind. Feb. 22, 2006) (finding plaintiff's common law negligence and fraud claims barred by the IPLA).

45. Product liability claims in Indiana are derived from the IPLA which "governs all actions that are (1) brought by a user or consumer; (2) against a manufacturer or seller; ... (3) for physical harm caused by a product regardless of the substantive legal theory or theories upon which the action is brought." Ind. Code § 34-20-1-1 et seq. (2008); *see also U-Haul Int'l, Inc. v. Nulls Machine & Mfg. Shop*, 736 N.E.2d 271, 281 (Ind. Ct. App. 2000) (holding that the IPLA subsumes negligence and strict liability claims in personal injury cases); *Ryan v. Philip Morris*, 2006 WL 449207, *2 (N.D. Ind. Feb. 22, 2006) (finding plaintiff's common law negligence and fraud claims barred by the IPLA).

46. The IPLA expressly limits liability to manufacturers or sellers of the alleged injury-causing product. Ind. Code § 34-20-2-2 et seq.; *see also* Ind. Code § 34-6-2-115 (defining a "product liability action" for purposes of Indiana Code § 34-20, as an action that is "brought against a manufacturer or seller of a product" and is "for or on account of physical harm"); *Williams v. REP Corp.*, 302 F.3d 660, 666 (7th Cir. 2002) (applying Indiana law) (holding that because defendant corporation did not sell, produce or otherwise put into the stream of commerce the machine that caused plaintiff's injury, it cannot be liable under the

IPLA); *Kennedy v. Guess, Inc.*, 806 N.E.2d 776, 780 (Ind. 2004) (stating that "actions for strict liability in tort are restricted to *manufacturers* of defective products. Indeed, the [IPLA] states the restriction rather bluntly.") (emphasis in original).

***8** 47. The IPLA's limits on liability arise out of a basic tenet of products liability law: that the seller and manufacturer of a product derive economic benefits from the sale of the product and, in the event the product causes injury, these economic benefits provide a justification for holding the seller and manufacturer liable. *See Williams v. REP Corp.*, 302 F.3d 660, 665 (7th Cir. 2002)(applying the IPLA to dismiss product liability claims against a defendant because the product at issue was not sold or manufactured by the defendant but was sold and manufactured by a different company that was owned by the same parent company as the defendant). A defendant that does not sell or manufacturer a product "does not derive economic benefits from the sale, and there is no reason that it should be held accountable for the other corporation's act ... we cannot ignore the language of the Indiana Products Liability Act." *Id.*

48. Consistent with the IPLA, a number of Indiana cases have granted summary judgment where the defendant established that the plaintiff did not use the defendant's product. *See, e.g., Asbestos Corp.*, 872 N.E.2d at 1098 (granting summary judgment for defendant because plaintiff designated no evidence to establish a genuine issue of material fact that plaintiff had been exposed to any product made by defendant); *U-Haul Int'I, Inc. v. Nulls Machine & Mfg. Shop*, 736 N.E.2d 271, 281 (Ind. Ct. App. 2000) (holding that a causal link between plaintiff's injury and defendant's product is "an essential element not only of a claim of strict liability, but also a claim sounding in negligence" and affirming summary judgment because plaintiff "failed to demonstrate a material issue of fact on the question of proximate cause.").

49. Since the PLA "provides the sole and exclusive remedy for personal injuries allegedly caused by a product" in Indiana, Lilly is entitled to summary judgment on all of Plaintiff's claims against Lilly related to Prozac(r). *Stegemoller v. AC and S, Inc.* 767 N.E.2d 974, 976 (Ind. 2002).

50. Product liability claims in California, however, are derived from common law. *Conte*, 168 Cal. App. 4th at 102 ("Our decision today is rooted in ... California common law.").

51. California does not have a statute like the IPLA that governs all claims brought for physical harm allegedly caused by a product and that specifically limits liability to manufacturers or sellers of the alleged injury-causing product.

52. Another significant difference between Indiana and California law is the availability in California of a claim for negligent misrepresentation.

53. Indiana does not recognize the tort of negligent misrepresentation except in the limited context of employee/employer relationships. *Eve v. Sandoz Pharm. Corp.*, 2001 U.S. Dist. LEXIS 4531, 85-88 (S.D. Ind. Mar. 7, 2001).

54. Furthermore, Indiana law does not recognize any cause of action for misrepresentation that is based on representations made to third parties. *Id.* (granting summary judgment for defendant on plaintiff's fraud claim and holding that "since plaintiffs have not demonstrated that [defendants] made any misrepresentations to them personally, their fraud claim fails") (citations omitted); *see also Bilimoria Computer Sys., LLC v. Am. Online, Inc.*, 829 N.E.2d 150, 155 (Ind. Ct. App. 2005) (affirming summary judgment for defendant on plaintiff's fraud claim because defendant had demonstrated that it had no contact with, and made no representations to, plaintiff); *Parks v. Danek Med., Inc*. 1999 WL 1129706 at *8 (N.D. Ind., 1999) ("As Parks has not shown that Indiana has adopted a theory of third party recovery, he must show *personal* reliance on an alleged concealment or misrepresentation to assert a fraud claim.") (emphasis in original); *Koehler v. Wyeth Labs.*, 1987 WL 47831 at *6 (S.D. Ind. 1987) ("Plaintiff thus advances a theory of third party recovery for intentional concealment, but offers no Indiana authority for the proposition that third parties allegedly injured as a result of nondisclosure may recover based on intentional fraud.").

***9** 55. *Conte* involved a negligent misrepresentation claim which (unlike in Indiana) is recognized by California law. *Conte*, 168 Cal. App. 4th at 102. That claim was based on representations that the defendant had allegedly made to physicians as opposed to representations allegedly made to the plaintiff. *Id.*

56. Indeed, the California Court of Appeals in *Conte* allowed the plaintiff to pursue only a claim for misrepresentation against Wyeth. *Id.* at 101 (stating that plaintiff would lose if she were "in fact pursuing a cause of action against Wyeth for strict products liability. But she is not.").

57. The *Conte* court specifically held that traditional products liability claims, whether in strict liability or negligence, may not be brought against a defendant that did not sell or manufacture the product at issue. *Id.*

58. Accordingly, *Conte* is inapposite because Plaintiff here did not, and may not, assert a negligent misrepresentation claim under Indiana law, and because Indiana law does not recognize a cause of action for misrepresentation that is based on alleged representations to third parties.

59. A third significant difference between Indiana and California law that requires the rejection of *Conte* relates to the concept of "duty."

60. In *Conte*, the California Court of Appeals found a duty when there was no relationship between the parties because, under that court's interpretation of California law, duty can be based solely on foreseeability. *Conte*, 168 Cal. App. 4th at 109. The court stated that in California, foreseeability is the principal determinant of duty where the risk created is one of personal injury. *Id.*

61. In contrast, under Indiana law a duty does not arise unless there is a relationship between the parties. *See Parsons v. Arrowhead Golf, Inc.*, 874 N.E.2d 993, 997 (Ind. Ct. App. 2007) (holding that the existence of a duty is a question of law, and depends "on the nature of the relationship, a party's knowledge, and the circumstances surrounding the relationship."). In Indiana, "a duty of reasonable care is not owed to the world at large, but must arise out of a relationship between the parties." *Id.*

62. There is no evidence in this case of any relationship between James Short and Lilly upon which a duty could be based with respect to Plaintiff's Prozac(r)-related claims.

63. Accordingly, even if Indiana law allowed a negligent misrepresentation claim to be brought outside of the employer/employee relationship, that claim would fail here for lack of duty. *See Ford Motor Co. v. Rushford*, 868 N.E.2d 806, 810 (Ind. 2007) (noting that under Indiana law, negligence requires proof of "(1) a duty owed by the defendant to the plaintiff; (2) a breach of that duty by the defendant; and (3) an injury to the plaintiff proximately caused by the breach.").

64. The Indiana Supreme Court has rejected other attempts by plaintiffs to hold one manufacturer liable for damages allegedly caused by another manufacturer's product through the use of "market share" liability. *See City of Gary v. Smith & Wesson, Corp.*, 801 N.E.2d 1222, 1245 (Ind. 2003).

65. Given the significant differences between Indiana and California law, this Court declines to follow the California Court of Appeals' decision in *Conte v. Wyeth*.

ORDER

The Court hereby GRANTS summary judgment in favor of Lilly on Plaintiff's Prozac(r)-related claims. There is no genuine issue of material fact in dispute, and Lilly is entitled to judgment on these claims as a matter of law. Lilly is entitled to summary judgment not only because Plaintiff failed to respond to and to timely designate evidence in opposition to Lilly's Motion, but also because Lilly negated essential elements of Plaintiff's claims. Product identification is an essential element of any product liability claim under Indiana law. Lilly has established, and Plaintiff has conceded, that James Short did not use brand-name

Prozac(r) manufactured by Lilly. For the foregoing reasons, Lilly's Motion for Summary Judgment on Plaintiff's Prozac(r)-Related Claims is GRANTED.

***10** SO ORDERED this *25th* day of *March*, 2009.

<<signature>>

Heather A. Welch, Judge

Marion County Superior Court 12

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Footnotes

1 As set forth below, Plaintiff's misrepresentation claim can only be brought as a claim for intentional misrepresentation because Indiana does not recognize the tort of negligent misrepresentation except in the limited context of employee/employer relationships. *Eve v. Sandoz Pharm. Corp.*, 2001 U.S. Dist. LEXIS 4531, 85-88 (S.D. Ind. Mar. 7, 2001). This case does not involve an employer/employee relationship; therefore, Plaintiff cannot assert a negligent misrepresentation claim.

2014 WL 8849464 (Kan.Dist.Ct.) (Trial Order)
District Court of Kansas.
McPherson County

Jerry ANSELMO and Mary Ellen Anselmo, Individually and as Plaintiffs Ad Litem for Brian Anselmo, Plaintiffs,
v.
SANOFI-AVENTIS INC. USA, Defendant.

No. 10-CV-77.
October 13, 2014.

Decision of the Court on Pending Matters

Richard B. Walker, Judge.

***1** The Court has now had an opportunity to consider all pending matters and motions in this case. Prior to ruling, I have read the file, considered the arguments of the parties, and conducted the research necessary to be able to rule on the matters presented. The decisions of the Court are set forth below,

NATURE OF THE CASE: This is a products liability action. Plaintiffs (hereafter Anselmos) are the surviving parents of Brian Anselmo of Lindsborg, Kansas, who is now deceased. Defendant Sanofi-Aventis is a drug manufacturer which produces, markets and sells the drug Ambien, which is prescribed for the treatment of insomnia. Anselmos initial petition alleged that Ambien was prescribed by a physician for the use of their son Brian, and that he died from the use of that drug. In Plaintiff's most recent iteration of their claims, the Second Amended Petition, Anselmos concede that Brian was prescribed and used the generic form of Ambien known as Zolpidem, which was not manufactured and sold by Sanofi-Aventis,

The Court has before it several motions which need to be determined. They will be dealt with individually as set forth below,

I. DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED PETITION. This motion to dismiss, filed pursuant to K.S.A. 60-212(b)(6), contends that the Second Amended Petition of the Plaintiffs fails to state a claim, upon which relief can be granted. Under that statute, a trial court should dismiss a petition only when it appears beyond doubt that the petitioner can prove no set of facts that would entitle it to relief. Any factual discrepancies must be viewed in a light most favorable to the Plaintiffs, and with every doubt resolved in Plaintiffs' favor. *Shepherd v. Davies*, 14 Kan.App. 2d, 333, 789 P.2d 1190 (1990)

The essential question raised by the motion in this case is whether, in a claim brought under the provisions of the Kansas Products Liability Act, K.S.A 60-3301 *et seq.* (hereafter KPLA), a name-brand drug maker such as Sanofi-Aventis can be held liable for injuries allegedly caused by a generic version of their drug, when the defendant neither manufactured nor sold the product to the injured party. This Court has come to the conclusion that it cannot be held liable.

Plaintiffs' claims for relief are brought under KPLA. The purpose of the KPLA is to consolidate all product liability claims, regardless of the underlying legal theory, into a single theory of liability. The definition of "product liability claim" under K.S.A. 60-3302 is very broad and was written by lawmakers to prevent litigation of multiplicitous products liability claims. See *Miller v. Lee Apparel Co., Inc.*, 19 Kan.App.2d 1015, 881 P.2d 576 (1994). Accordingly, Plaintiffs' multiple theories for liability, including negligent drug design, are treated as a single product liability claim under KPLA. Plaintiffs' claims can be brought exclusively under KPLA and are subject to any statutory limitations under KPLA. See *Patton v. Hutchinson Wil-Rich Mfg. Co.*, 253 Kan. 741, 861 P.2d 1299 (1993).

***2** In support of its motion to dismiss, Defendant correctly notes that under KPLA, a party is liable only for injuries caused by products it sold an/or manufactured. Courts interpreting the KPLA have supported the idea that "if a plaintiff cannot prove that the relevant product was manufactured or sold by the defend, the plaintiff cannot prevail" See *Alvarado v. J.C. Penney Co., Inc.*, 768 F. Supp. 769 (D. Kan. 1991). In *Deines v. Vermeer Mfg. Co.*, 752 F. Supp. 989 (1990), it was held that where a defendant is not a "manufacturer" or "product seller" within the meaning of the KPLA, that Act was inapplicable to determine liability.

In opposing the motion, Plaintiffs rely primarily on a non-Kansas case, *Conte v. Wyeth Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008), which held that brand drug manufacturer Wyeth owed a duty to the plaintiff even though the plaintiff never ingested drugs made by Wyeth. The Court found that Wyeth knew or should have known that a significant number of patients' doctors relied on its product information when they prescribed the generic drug. See *Levine v. Wyeth Inc.*, 684 F. Supp. 2d 1338 (M.D. Fla., 2010) citing *Conte.*

In the opinion of this Court, *Conte* is clearly distinguishable from this case. California product liability law differs from the significant majority of states, including Kansas, in that it does not "collapse" all theories of recovery into a single product liability claim. As noted by the *Conte* court:

> "Negligence and strict products liability are separate and distinct bases for liability that do not automatically collapse into each other… Accordingly,… this is a case involving legal principles of negligent misrepresentation, *not* a products liability action." *Conte* at 107.

While the *Conte* court held the brand name manufacturer liable only for negligent misrepresentation, with the single claim not collapsed into product liability law, it also expressly stated that such a generic liability theory would *not* be viable under other sate laws where all claims collapsed into one product liability cause of action. *Conte*, at 101-102. Notably, Plaintiffs' only other supporting case hails from another state similarly at odds with the product liability practices of the majority of states. See *Kellogg v. Wyeth Inc.*, 612 F. Supp. 2d 437 (D. Vt., 2009) But, unlike the legal environment of KPLA, neither Vermont courts nor the Vermont Legislature have collapsed negligence actions into strict liability action where products are involved.

As noted by Defendant, Plaintiffs' generic liability theory has been overwhelmingly rejected by over forty courts in more than twenty states. The citations are listed in the defense brief and will not be set out further here. These courts have reached a common conclusion: a brand name manufacturer cannot be held liable for injuries allegedly caused by a generic manufacturer's product. Based upon the similarities between the KPLA and these majority states' statutes, this Court feels compelled to reach a similar conclusion.

The policy rationale for this position was set out clearly in the *Levine* case, cited above: "It would be simply improper for this court to expand liability to manufacturers [like defendant] who do not have a direct relationship with the Plaintiff and who play no role in the production of the actual [injury-causing] product. To do so would unfairly render every manufacturer a virtual insurer of all like products on the market." *Levine*, 684 F. Supp. 2d. at 1347. This is especially unfair when the generic manufacturer reaps the benefits of Defendant's statements by copying its labels, riding the coattails of its advertising) and acting as a direct competitor in the marketplace, taking sales and profit away from a defendant while using the formula that defendant spent its own. capital to develop. See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994).

***3** In further opposition to the Motion to Dismiss, Plaintiffs assert that a cause of action for negligent design is well established in Kansas tort law. This statement is correct, but it avoids the pertinent issue in this case. Defendant does not dispute that such a cause of action exists, but correctly notes that it is included under the umbrella of KPLA. As noted in *Savina v. Sterling Drug, Inc.*, 247 Kan. 105, 795 P. 2d 915 (1990), a product is considered "defective" and is actionable under Kansas law if the product, although perfectly manufactured, contains design defects making it unsafe. Further, Kansas laws recognize only three ways in which a product may be defective, and thus actionable: in manufacturing, warning or *design.* See *Delaney v. Deere and Co.*, 268 Kan. 769, 999 P.2d 930 (2000).

But the real question in this case is not whether Plaintiff has a valid KPLA claim, but whether if can be brought against this Defendant. Defendant contends it cannot be liable for injury caused by a product which it neither manufactured nor sold. If there is no liability, then the motion to dismiss must be granted.

In responding to the defense motion to dismiss, Plaintiff cited several Kansas cases in support of its "negligent design" theory. These include *Miller v. Lee Apparel Co., Inc.*, cited above, which held that in Kansas a duty exists to use reasonable care in designing products for consumer use. Also cited is *Garst v. General Motors Corp.*, 207 Kan. 2,484 P.2d 47 (1971), holding that there exists a duty to use reasonable care in the design of products so they will be reasonably safe for use which can be reasonably anticipated; and *Griffin v. Suzuki Motor Corp.*, 280 Kan. 447, 124 P.3d 57 (2004) decreeing that when a design defect makes a product unreasonably dangerous, a plaintiff can recover for the injuries caused by such defect.

All of these cases appear to this Court to be clearly distinguishable. In each of the above cases it was clearly shown that the defendants were the manufacturers of the products at issue. There is no evidence in this case that Sanofi-Aventis actually manufactured the drug which was taken by Brian Anselmo.

Finally, Plaintiffs seek to rely on the Texas case of *Alm v. Aluminum Co. of America*, 717 S.W.2d 588 (Sup, Ct. Tx. 1986) for the proposition that there is liability for the designer of a product even when it was manufactured by another. At first glance, this assertion seems to be accurate:

> "A designer who is not also the manufacturer should also share the same duty to develop a safe design … There is no reason to distinguish a designer, who has intimate knowledge of a designed product, from a retailer, wholesaler or manufacturer. [Defendant] designed the system. It is the failure of that system which caused Aim's injury. There can be no justification for requiring a user of [Defendant's] technology to warn of its hazards while not holding [Defendant] to the same duty." *See Alm*, at 591.

However, *Alm's looks* can be deceiving, and a closer inspection reveals it to be just as inapplicable as the other cases cited by Plaintiffs. In *Alm*, the plaintiff sustained an injury when the aluminum cap on his bottle of 7-Up exploded off the bottle and struck him in the eye. He sued multiple entities, including the defendant, who designed, manufactured and sold the capping equipment used by the soda manufacturer. The court found that the defendant could be liable for injuries to the plaintiff because it was "the designer, manufacturer, and seller of the capping machine."

The crucial distinction is that the defendant actually did manufacture and sell the capping system that caused the defective injury-causing caps to be placed on the final product. No such connection exists in this case.

***4** In addition to directly manufacturing the defective caps on the soda bottles, the defendant in *Alm* also stood to profit through its relationship with the soda producer/bottler. The two defendant there worked together for mutual financial benefit. In this case, to the contrary, Sanofi-Aventis and the manufacturers of the generic drug are direct competitors. Making Defendant Sanofi-Aventis the 'virtual insurer" of its competitors makes no policy sense whatsoever.

Plaintiffs additionally claim the negligent design theory in the context of breaching a duty by failing to warn consumers about known dangers associated with a product. Its brief quotes the Restatement (Second) of Torts, which assigns such a duty "to sellers,… irrespective of whether the chattel is made by them or by a third person." Restatement (Second) of Torts, Sec. 388, Comment "c". However, this Restatement section clearly appears to this Court to be intended to apply specifically to parties who sell or otherwise pass a product down a distribution chain to a future/end user. Further, it focuses on "sellers," a class of defendant who are subject to liability under the KPLA. In this case, Sanofi-Aventis is not a seller, nor did it share a distribution chain with the Plaintiffs, In either case, the Restatement appears clearly inapplicable.

Having reached the above conclusions, it appears that the Second Amended Petition of the Plaintiff clearly fails to state a cause of action against Defendant Sanofi-Aventis. For this reason, the Motion to Dismiss under K.S.A. 60-2*l*2(b)(6) must be granted.

II. DEFENDANTS' MOTION FOR LEAVE TO FILE A THIRD AMENDED COMPLAINT. In this motion, the Defendants are requesting the Court grant permission for the filing of a third amended petition. As originally proposed, the plaintiff wished to implead the additional parties identified as Ranbaxy Laboratories Limited and similar affiliated Ranbaxy companies into the case. Plaintiffs allege that the Ranbaxy companies manufactured and marketed the generic form of Zolpidem which was actually ingested by Brian Anselmo.

Additionally, plaintiffs sought to add an additional cause of action against Sanofi-Aventis on a theory of negligence related to an alleged duty of Sanofi-Aventis "to dispense information to all foreseeable users and prescribers of the drug Ambien, or their generic bio equivalents."

However, in communications with this Court the plaintiffs now concede that their proposed cause of action against the Ranbaxy defendants are now barred outright as a result of the 2011 decision of the United States Supreme Court in *Pliva Inc. et al. v. Mensing*, 131 S. Ct 2567. The court in *Pliva* held that federal preemption immunizes generic drug manufacturers from liability for state law failure to warn claims. As a result, consumers harmed by a mislabeled generic drug cannot bring actions against a generic drug manufacturer under state law. The Court found that because the FDA regulations require that labels on a generic drug be identical to its brand name counterpart, federal law preempts State court failure to warn claims.

Based upon the *Pliva* decision, it is now plain that the proposal to add the Ranbaxy companies as fellow defendants with Sanofi-Aventis is doomed to failure, and therefor should not be permitted.

As noted the plaintiffs also wish to add a negligence claim against Sanofi-Aventis as part of their proposed third amended petition. Without repeating all of the finding this Court made above, I believe this claim lack merit and the proposed amendment will be denied.

***5** Regardless of how artfully the claims against Sanofi-Aventis are clothed by the plaintiffs, it is clear that they have a but a single cause of action because of the specific language of the KPLA. In my ruling on the first issue, resulting in the dismissal of the plaintiffs' prior negligent design claims against Sanofi-Aventis, I granted dismissal since Sanofi-Aventis is neither a manufacturer nor seller of the generic Zolpidem ingested by Brian Anselmo. I am not persuaded by the plaintiffs' recasting of this as a negligence claim for allegedly failing to dispense information concerning Ambien that they have been able to extricate their lawsuit from under the broad scope of the KPLA. My above decisions appear apt in analyzing this most recent claim, and I decline to allow the plaintiffs to file a third amended complaint containing those claims.

III. FINAL ORDERS OF THE COURT. Having made the decisions described above, it appears to the Court that the issues in this case are at an end. Sanofi-Aventis is ordered dismissed as a party defendant, Ranbaxy Laboratories and its related companies cannot be added as parties. Further amendment to the plaintiffs' claims has been denied. Therefor, this entire lawsuit is ordered dismissed, with prejudice.

For purposes of appeal this decision shall be considered final on the date it is filed with the Clerk of the District Court of McPherson County. No further journal entry shall be required.

IT IS SO ORDERED.

<<signature>>

RICHARD B. WALKER

District Judge

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2009 WL 3806716
Only the Westlaw citation is currently available.
United States District Court, S.D. West Virginia.

Shirlean MEADE and Elmer Meade, Plaintiffs,
v.
Deidre E. PARSLEY, D.O.; Wyeth, Inc., doing business as Wyeth; Schwartz Pharma, Inc.; Pliva, Inc.; and John Doe Defendants # 1–6, Defendants.

Civil Action No. 2:09–cv–00388.
|
Nov. 13, 2009.

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MEMORANDUM OPINION AND ORDER

JOHN T. COPENHAVER, JR., District Judge.

***1** Pending is the Joint Motion for Summary Judgment of defendants Wyeth, Inc., and Schwarz Pharma, Inc., filed July 31, 2009. [1]

I.

Plaintiffs initiated this action against defendants Wyeth, Schwarz, Pliva and six fictional defendants, all alleged to be manufacturers of the pharmaceutical metoclopramide. Wyeth manufactured and distributed metoclopramide under the brand name Reglan from approximately 1989 through late December 2001. (Mot.Summ .Jgt.3). Schwarz acquired the rights to Reglan in late December 2001, and manufactured and distributed it until 2008. (Mot.Summ.Jgt.3). Plaintiffs refer to the drug throughout their complaint as "Reglan/metoclopramide," but they concede that Mrs. Meade never purchased nor ingested Reglan. (Resp. to Mot. Summ. Jgt. 1).

Since the mid-eighties, other drug companies have manufactured and distributed generic versions of Reglan. (Mot.Summ.Jgt.3). Plaintiffs allege that defendants Pliva and the six fictitious parties, or the "generic defendants" as they are referred to in the complaint, are such generic manufacturers. Plaintiffs bring suit against not only the generic manufacturers but also the brand name manufacturers, Wyeth and Schwarz, based on the following facts.

From January 2006 to February 2007, Mrs. Meade's physician prescribed to her Reglan to treat her reflux disease. (Compl.¶¶ 34, 40). Mrs. Meade's pharmacist filled her Reglan prescription with one of the generic versions of metoclopramide, presumably

manufactured by one of the "generic defendants," "as required by the generic laws in the State of West Virginia." (Resp. to Mot. Summ. Jgt. 19–20).

While taking metoclopramide, Mrs. Meade developed symptoms of the neurological disorders tardive dyskinesia and akathisia. [2] (Compl.¶¶ 31, 38, 39). The symptoms of these disorders include "involuntary and uncontrollable movements of the head, neck, face, arms, legs and trunk in addition to grotesque facial grimacing and open-mouthed, uncontrollable tongue movements, tongue thrusting, tongue chewing, and other involuntary movements." (Compl.¶ 31). Mrs. Meade's symptoms were diagnosed on or about April 2, 2007. (Compl.¶ 41).

In their complaint, plaintiffs allege 13 counts of wrongdoing against defendants under theories of strict product liability, breach of express and implied warranties, negligence, misrepresentation, fraud, the West Virginia Unfair Trade Practices Act and intentional infliction of emotional distress.

Plaintiffs initiated this action in the Circuit Court of Mingo County on February 25, 2009. Defendants timely removed on April 20, 2009, on the grounds of diversity jurisdiction. (Not. of Removal 2). On July 31, 2009, defendants Wyeth and Schwarz moved for summary judgment on the grounds that they are not liable for damages caused by another manufacturer's product. A party is entitled to summary judgment "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). There is no genuine issue as to any material fact here.

II.

***2** In their motion for summary judgment, Wyeth and Schwarz note that Reglan, their product, was never ingested by Mrs. Meade and they argue that they are thus not liable to plaintiffs for the claims alleged. (Mot.Summ.Jgt.1). Plaintiffs, on the other hand, describe this action as a "failure to warn case," rather than a product liability action, and argue that Wyeth and Schwarz, as the original manufacturers, had a duty to "ensure their warnings to the medical community [were] accurate and adequate...." (Compl. ¶¶ 57–60; Resp. to Mot. Summ. Jgt. 1).

Plaintiffs' claims against Wyeth and Schwarz are based on underlying Federal Drug Administration ("FDA") regulations regarding innovator and generic drug manufacturers. (Resp. to Mot. Summ. Jgt. 3). In short, plaintiffs assert that if generic manufacturers affirm that their product is identical to the corresponding brand name drug, they can get FDA approval without submitting independent evidence of safety and efficacy, and the generic manufacturers essentially adopt the brand name manufacturers' label, including their warnings. (Resp. to Mot. Summ. Jgt. 4). *See Foster v. American Home Products Corp.,* 29 F.3d 165, 168 (4th Cir.1994) (citing 21 U.S.C.A. § 355(j)(2)(A)(v)). Plaintiffs further assert that inasmuch as generic manufacturers are permitted to rely on brand name manufacturers' warnings, the brand name manufacturers are ultimately liable for inaccuracies and deficiencies in their safety information, regardless of whether the brand name or generic drug was ingested. (Resp. to Mot. Summ. Jgt. 9).

III.

Despite the plaintiffs' alleged reliance, or vicarious reliance through Mrs. Meade's physician, on Wyeth and Schwarz's representations with respect to Reglan, and despite the many theories of liability plaintiffs set forth, Wyeth and Schwarz are not responsible for the damage resulting from a product that they did not manufacture, distribute or sell. This is directly in line with our court of appeals's decision in *Foster v. American Home Products. Foster* is the leading authority for the line of cases rejecting the claim that a manufacturer of a brand name drug is responsible for misrepresentations when a generic manufacturer's product caused the plaintiff's injury. *See Stoddard v. Wyeth, Inc .,* 630 F.Supp.2d 631, 634 (E.D.N.C.2009) (adopting *Foster's* reasoning with respect to Wyeth and generic metoclopramide); *Fields v. Wyeth,* 613 F.Supp.2d 1056, 1061 (W.D.Ark.2009) (following

Foster and concluding that "the party that actually controls the manufacturing and labeling of the product in question, and enjoys the profit of its sale, should bear legal liability for any resulting injury"); *Swicegood v. Pliva, Inc.,* 543 F.Supp.2d 1351, 1358 (N.D.Ga.2008) (concluding that a manufacturer of a brand name product is not liable for misrepresentations in the generic product's label); *Colacicco v. Apotex, Inc.,* 432 F.Supp.2d 514, 540 (E.D.Pa.2006) (noting *Foster's* "widespread acceptance" and citing other cases that adopt its reasoning), *aff'd* on other grounds, (3d Cir.2008), vacated on other grounds, *cert. granted,* 77 U.S.L.W. 3499 (U.S. Mar. 9, 2009) (No. 08–437).

***3** In *Foster,* the plaintiffs appealed the district court's judgment concerning their negligent misrepresentation claim against the brand name manufacturer of a drug, the generic version of which, plaintiffs alleged, caused the death of their daughter. *Id.* at 166, 167–68. Earlier in the proceedings, the district court granted the brand name defendant summary judgment on the plaintiffs' negligence, strict liability and breach of warranty counts inasmuch as the defendant was not the manufacturer of the drug that was actually taken. *Id.* at 167.

The Fourth Circuit concluded that a brand name manufacturer's representations about its own product cannot serve as a basis of liability for damages caused by a generic manufacturer's product. *Id.* at 170. The *Foster* court noted that the brand name defendant was under no duty of care to the plaintiffs when the brand name drug was never used, and that "When a generic manufacturer adopts a brand name manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed." *Id.* at 169.

Foster was based in Maryland product liability law, but West Virginia law does not yield a different result. Product liability law in West Virginia allows for recovery when the plaintiff can prove that "a product was defective when it left the manufacturer and the defective product was the proximate cause of the plaintiff's injuries." *Dunn v. Kanawha County Bd. of Educ.,* 194 W.Va. 40, 459 S.E.2d 151, 157 (1995) (citing *Morningstar v. Black & Decker Mfg. Co.,* 162 W.Va. 857, 253 S.E.2d2d 666, 677 (1979). Because neither Wyeth nor Schwarz manufactured the product that injured plaintiffs, there is no proximate cause.

Plaintiffs nevertheless rely on *Conte v. Wyeth, Inc.,* 168 Cal .App.4th 89, 85 Cal.Rptr.3d 288 (Cal.Ct.App.2008). The facts of *Conte* are identical to those of this case. The plaintiff developed tardive dyskinesia after taking a generic form of metoclopramide and brought suit against Wyeth for its representations of Reglan. *Id.* at 305. The court in *Conte* allowed the plaintiff to go forward, not on a product liability theory, but on a negligent misrepresentation theory so that she might establish Wyeth's liability by proving that her treating physician relied on Wyeth's warnings when prescribing Reglan to the plaintiff. *Id.* at 310–11.

So far, *Conte,* which recognized but declined to follow *Foster,* is the only decision in several like actions that has allowed the plaintiff to proceed against Wyeth when only the generic version of the drug was ingested. Our court of appeals in *Foster* has addressed this issue, making the negligent misrepresentation theory of liability unavailable to plaintiffs seeking damages against brand name defendants when their injuries resulted from another manufacturer's product. Inasmuch as the remaining claims against Wyeth and Schwarz require a duty of care to the plaintiffs or proximate cause, summary judgment is proper as to Wyeth and Schwarz.

IV.

***4** It is, accordingly, ORDERED that Wyeth's and Schwarz's motion for summary judgment be, and it hereby is, granted. It is further ORDERED that Wyeth and Schwarz be, and they hereby are, dismissed from this action.

The Clerk is directed to forward copies of this written opinion and order to all counsel of record and any unrepresented parties.

All Citations

Not Reported in F.Supp.2d, 2009 WL 3806716

Footnotes

1 "Schwarz Pharma, Inc." is the correct spelling of the defendant named in the case style as "Schwartz Pharma, Inc." The clerk is directed to amend the style accordingly.

2 The alleged connection between long-term use of metoclopramide and neurological disorders is not unique to this case. Metoclopramide affects the nervous system by blocking receptors of dopamine, the chemical that sends signals between nerves, in the brain. *See McNeil v. Wyeth,* 462 F.3d 364, 366 (5th Cir.2006). Many patients who have been prescribed a form of metoclopramide developed neurological disorders and subsequently brought suit against the manufacturers of the drug. *See, e.g., McNeil,* 462 F .3d 364; *In re Reglan/Metoclopramida Product Liability Litigation,* 622 F.Supp.2d 1380 (U.S.J.P.M.L 2009); *Stoddard v. Wyeth, Inc.,* 630 F.Supp.2d 631 (E.D.N.C.2009); *Fields v. Wyeth, Inc.,* 613 F.Supp.2d 1056 (W.D.Ark.2009); *Schrock v. Wyeth, Inc.,* 601 F.Supp.2d 1262 (W.D.Okla.2009); *Morris v. Wyeth, Inc.,* 642 F.Supp.2d 677, 2009 WL 424590 (W.D.Ky.2009); *Wilson v.. PLIVA, Inc.,* 640 F.Supp.2d 879 (W.D.Ky.2009); *Kellogg v. Wyeth,* 612 F.Supp.2d 421 (D.Vt.2008); *Demahy v. Wyeth Inc.,* 586 F.Supp.2d 642 (E.D.La.2008); *Morris v. Wyeth,* 582 F.Supp.2d 861 (W.D.Ky.2008); *Mensing v. Wyeth, Inc.,* 562 F.Supp.2d 1056 (D .Minn.2008); *Swicegood v. Pliva, Inc.,* 543 F.Supp.2d 1351 (N.D.Ga .2008). Indeed, Wyeth has been a party to nearly all of these cases.

2004 WL 4056060
Only the Westlaw citation is currently available.
District Court of Colorado, El Paso County.

Sidney and Judith SHEEKS, Plaintiffs
v.
AMERICAN HOME PRODUCTS CORPORATION, et al Defendants

No. 02CV337.
|
Oct. 15, 2004.

Order

SAMELSON, J.

***1** I have reviewed Defendant Wyeth's Motion for Summary Judgment, the Response, Reply and Surreply, Plaintiffs have alleged two causes of action against Wyeth, negligent misrepresentation and products liability. Plaintiffs allege that Plaintiff Sidney Sheeks was prescribed and took a medication generically known as metoclopramide, also known under Wyeth's brand name of Reglan, and as a result of that prescription drug, developed a neurological disorder. Wyeth moved for summary judgment based on three arguments: 1) that Sidney Sheeks did not use Reglan, 2) there is no admissible evidence that Reglan caused Mr. Sheeks damages, and 3) that Wyeth is not liable for any misrepresentations contained in Reglan labeling because Mr. Sheeks used a generic version of the drug.

Standards of Review. Summary Judgment is proper only if there are no issues of material fact in dispute and the moving party is entitled to judgment as a matter of law. *Churchey v. Adolph Coors Co.* 759 P.2d 1336 (Colo.1988). If the moving party meets its initial burden, then the burden shifts to the opponent to establish that there is a triable issue of fact. *Artes-Roy v. Aspen,* 856 P .2d 823 (Colo.1993). CRCP 56(e) provides in part "When a Motion for Summary Judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the opposing party's pleadings, but the opposing party's response by affidavits or otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue of trial."

Use of Reglan and Proximate Cause. The only evidence presented that Mr. Sheeks took Reglan is a hearsay statement through Mrs. Sheeks that a doctor and nurse told her that Mr. Sheeks had taken Reglan prior to or during surgery in 1996 and 1998, and that Dr. Shafii had given Mr. Sheeks samples of Reglan in 1997. None of the medical records provided indicate that Mr. Sheeks took Reglan. Furthermore, inadmissible hearsay cannot be used to defeat summary judgment, absent any other evidence of disputed material facts. *Terrones v. Tapia,* 967 P.2d 216 (Colo.App.1998). Mrs. Sheeks testified that the samples of Reglan given to her husband in 1997 were blue capsules or pills. The evidence presented by Wyeth shows that Wyeth did not provide any Reglan samples to doctors after the early 1990s, and when they had been distributed, they were green or white tablets. There are no disputed issues of material fact regarding whether or not Mr. Sheeks took Reglan. All admissible evidence indicates that he did not. Therefore, Plaintiffs are precluded from using the argument that Mr. Sheeks took Reglan, and its use was the proximate cause of his damages.

Liability for Labeling of Generic Metoclopramide. Plaintiffs argue that even without evidence that Mr. Sheeks ingested Reglan, Wyeth is liable for any misrepresentations made in the labeling of generic metoclopramide, even though Wyeth did not manufacture the generic drug. Regardless of how termed, the action brought by the Sheeks is a product liability action (CRS 13-21-401). There is no dispute that the metoclopramide ingested by Mr. Sheeks was not manufactured or sold by Wyeth. "Under Colorado statutory law, product liability is imposed on a 'manufacturer' of the product" *Yoder v. Honeywell, Inc.,* 900

F.Supp.240 (D.Colo.1995). Plaintiffs argue that this legal precept should be expanded so that the courts look at a claim of negligent representation separate from the product liability claim.

***2** The only reported cases directly on point with the facts of this case are *Foster v. American Home Products Corp.* 29 F.3d 165 (4th Cir.1994) and *Block v. Wyeth, Inc. et al,* 2003 U.S. Dist. Lexis 1169 (N.D.Tex.2003). In those cases the Courts did not allow a negligent misrepresentation claim against an original prescription drug manufacturer for labeling of its drug, when the evidence showed that the Plaintiff ingested a generic equivalent of the original manufacturer's drug. The generic drugs were not manufactured by the companies against whom the Plaintiffs sought relief. Plaintiff tries to distinguish those cases by cites to Colorado cases, *Bloskas v. Murray, M.D.,* 646 P.2d 907 (Colo.1982) and *Bailey v. Huggins Diagnostic & Rehabilitation Center, Inc*. 952 P.2d 768 (Colo.1997). The facts of those cases are dissimilar to the facts in this case. In the *Bloskas* case, the Court recognized the tort of negligent misrepresentation. The *Bailey* case discusses factors to be considered in determining if a defendant owed a duty of care to the Plaintiff for negligent misrepresentation. *Bailey* was not a product liability case, however. It was a malpractice case. Neither case attempted to hold an entity who did not manufacture a product, liable for that product. Those cases are not dispositive of the facts of this case. Neither case presents cogent arguments as to why a negligent misrepresentation claim in the context of product liability, is not subsumed in the product liability claim.

Even if I disregard Colorado law, and consider the negligent misrepresentation claim separate from the product liability claim, the result is no different. I have considered the factors set out in *Bailey,* the social utility of Defendant's activity, the magnitude of the burden of guarding against the harm, the consequences of placing that burden the Defendant, and the individual and social interests implicated by the conduct. The same factors set forth by the Court in *Foster* apply to this case, and the Court's reasoning is persuasive. I find that Wyeth owed no duty to Plaintiffs to warn of a drug that it did not manufacture or supply. Wyeth's Motion for Summary Judgment is Granted.

All Citations

Not Reported in P.3d, 2004 WL 4056060

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2007 WL 7632318 (N.J.Super.) (Trial Order)
Superior Court of New Jersey.
Atlantic County

ROSSI,
v.
HOFFMANN-LAROCHE, et. al.

No. ATL-L690-05.
January 3, 2007.

Motion: Defendant Hoffmann-La Roche, Inc. and Roche Laboratories Inc.'s Motion for Summary Judgment Defendant Hoffmann-La Roche, Inc. and Roche Laboratories Inc's Motion for Sanctions Defendant F. Hoffmann-La Roche Ltd.'s Motion for Summary Judgment Defendant Sandoz Inc.'s Cross Motion for Summary Judgment

Not for Publication Without the Approval of the Committee on Opinions

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MEMORANDUM OF DECISION ON MOTION

Pursuant to Rule 1:6-2(f)

Having carefully reviewed the papers submitted and any response filed, I have ruled on the above Motion as follows:

Defendants Hoffman-LaRoche, Inc. and Roche Laboratories, Inc. bring this motion for summary judgment. Defendant F. Hoffman-LaRoche Ltd. joins in this motion [hereinafter

[illegible text] *"The Judiciary of New Jersey is an equal Opportunity/Affirmative Action Employer"*6 collectively referred to as "Roche']. Further, Hoffman-LaRoche, Inc. and Roche Laboratories Inc. request sanctions to be imposed against Defendant Sandoz, Inc. Defendant Sandoz opposes each motion filed by the Roche Defendants and brings a motion for summary judgment against plaintiff. Plaintiff opposes Sandoz's motion.

BACKGROUND

Lariam® is a prescription drug manufactured by Roche. Lariam® is specifically produced as an antimalarial drug and has been marketed and manufactured by Roche since 1989. In May 2002, Sandoz began commercially distributing a generic equivalent of Lariam® called Mefloquine (mefloquine hydrochloride).

Plaintiff Dennis Rossi alleges that he obtained mefloquine hydrochloride in preparation for a trip to Africa and used the drug as he was instructed. Plaintiff alleges that after arriving in Africa he began to experience tinnitus, hearing problems, panic attacks, anxiety, mood swings, paranoia, insomnia, and depression. Plaintiff alleges that while these conditions were ongoing, he continued to ingest the drug because he was not informed of the risks of taking mefloquine hydrochloride and therefore failed to recognize the symptoms as potential side effects to the drug.

Since returning to the United States, Plaintiff alleges that he has continued to suffer from insomnia, paranoia, mood swings, visual disturbances, panic attacks, depression, confusion, psychotic episodes, and vestibular problems. Further, it is alleged that Plaintiff was diagnosed with "Lariam toxicity" and is currently disabled from working and unable to maintain a normal life. Plaintiff asserts that he continues to receive medical treatment as a result of his alleged injuries.

Plaintiff originally brought this claim solely against Roche because he believed that he had ingested Lariam. Further investigation led to the finding that Plaintiff actually ingested Mefloquine as manufactured by Sandoz. Following the discovery of this information, Plaintiff amended his complaint to include both Roche and Sandoz.

Roche now brings a motion for summary judgment against Defendant Sandoz. In brining this motion, Roch relies on several out of jurisdiction and one New Jersey Superior Court case that held that the manufacturer of a name brand prescription drug cannot be held liable for injuries allegedly caused by the ingestion of a generic version of the drug that was manufactured and marketed by a different company. [1] Roche further asserts, with regard to Sandoz's cross claims, that it is unaware of any legal authority that eliminates the duty of a generic prescription drug manufacturer to its customers or that would shift this burden to the maker of the name brand drug,

Further, Roche moves to strike each of Sandoz's cross claims as legally and factually baseless and deficient on its face. Sandoz has filed a motion for partial summary judgment against Plaintiff. Sandoz moves for summary judgment against Plaintiff. [2] Sandoz also seeks indemnification from Roche.

SUMMARY JUDGMENT

A party's motion for summary judgment should be granted when there is no genuine issue of material fact to be determined at trial and the law supports the movant's claims based on the undisputed facts. *R.* 4:46-2(c) provides that summary judgment can only be granted if, "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." Summary judgment should be denied if a rational fact-finder, when viewing the facts in the light most favorable to the non-moving party, could conclude that a genuine issue of material fact exists. *Brill v. Guardian Life Ins. Co. of America,* 142 N.J. 520, 540 (1995). Determinations of credibility should be made by a jury and not a judge. *Ibid.* It is also a task for the jury to weigh the evidence and determine the outcome; the judge should only determine whether there exists a material factual dispute. *Singer v. Beach Trading Co., Inc.,* 379 *N.J. Super.* 63, 72 (App. Div. 2005).

Further, it should be noted that New Jersey courts will "seek to afford 'every litigant who has a bona fide cause of action to defense the opportunity for full exposure of his case." *Velantzas v. Colgate-Palmolive Co.,* 109 N.J. 189, 193 (N.J. 1988) (quoting *United Rental Equip. Co. v. Aetna Life and Casualty Ins. Co.,* 74 N.J. 92, 99 (1977)). Further, the New Jersey Supreme Court has held that "[w]hen 'critical facts are peculiarly within the moving party's knowledge,' it is especially inappropriate, to grant summary judgment when discovery is incomplete." *Velantzas v. Colgate-Palmolive Co.,* 109 N.J. 189,193 (N.J. 1988) (quoting *Martin v. Educational Testing Serv., Inc.,* 179 *N.J. Super.* 317, 326 (Ch.Div. 1981)).

Sandoz Claim for Partial Summary Judgment Against Plaintiff

Sandoz brings this motion for partial summary judgment on Counts Two, Three, Five, and Six.

Count Three

Count Three raises a "wrongful misrepresentation/concealment" claim. This is not tenable as a separate and distinct claim and will be subsumed into Count Two or Count Six. For this reason, summary judgment will be granted as to Count Three as a separate cause of action, but the claims in Count Three become part of cause of action in Counts Two and Six.

Count Two

Count Two of Plaintiff's Amended Complaint alleges that Sandoz is liable for failure to warn under *N.J.S.A.* 2A:58C-2 et seq. While the statute allows for a failure to warn cause of action, it also provides that:

> the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction.

Sandoz asks this Court to find the warning adequate as a matter of law. In support of its motion, Sandoz cites *Banner v. Hoffman LaRoche Inc.,* which indicates that a court is in fact permitted to find a warning adequate as a matter of law. 383 *N.J. Super.* 364, 378 (App. Div. 2006) (finding that "[e]ven in the context of prescription drugs, the adequacy of a warning may be determined as a matter of law."). Sandoz rests much of its argument regarding this issue upon the theory that the PLA creates a rebuttable presumption that a warning approved by the FDA is adequate.

Rebuttable presumptions, however, are just as the name suggests, rebuttable. The opposing party has an opportunity to show that the presumption is incorrect. In the context of a summary judgment motion, the court must view the facts in the light most favorable to the plaintiff. If the Plaintiff can overcome the presumption of adequacy, then Sandoz's motion on this point must fail.

Further, while the case cited by Sandoz does indicate that a court is permitted to find the warning adequate as a matter of law, the determination in *Banner* was not made merely because the FDA approved the warning. The court in *Banner* examined the warnings and found them to be "accurate, clear, and unambiguous," and, therefore, judged them to be adequate as a matter of law. *Id.* at 382. Here, movant did not provide the court with any justification as to why the warnings should be found adequate other than to assert the presumption of adequacy and that it was unable to change the labels even if it had reason to do so.

The Court is not persuaded by Sandoz's assertion that it was unable to make changes to the label. This assertion is undermined by Sandoz's own brief In a footnote, Sandoz quotes the Abbreviated New Drug Application Rules (final rule), Comment on the Proposed Rule, 57 *Fed. Reg,* at 17,957, as stating that "[a]n ANDA applicant who believes that the labeling for a proposed drug produce should differ from that approved for the reference listed drug should contact FDA to discuss whether labeling for both generic and listed drugs should be revised." The brief then goes on to state that "generic manufacturers therefore cannot change a label without prior FDA approval." These statements are irreconcilable. There was, in fact, an avenue available for Sandoz to request changes in the warning if it felt the need.

Further, as the Court in *Foster* held, "[w]hen a generic manufacturer adopts a name brand manufacturers warnings and representations without independent investigation, it does so at the risk that such warnings and representations maybe flawed." *Foster, supra,* 29 *F.3d* at 169. The New Jersey Supreme Court has also noted a duty of a manufacturer to keep abreast of potential dangers that ensue post release of a drug. See *Feldman v. Lederle Laboratories,* 97 N.J. 429, 454 (1984) (citing McKee v. Moore, 648 *P.2d* 21, 24 (Okla.1982) (finding "a duty to warn requires prescription drug manufacturer to maintain current information 'gleaned from research, adverse reaction reports, scientific literature and other available methods." *Feldman,* 97 N.J. at 454)). This Court cannot find, as Sandoz suggests, that a generic manufacturer should be permitted to hide behind the warning created by the name brand manufacturer to avoid liability when the product that it manufactures causes injury. *See Foster,* 29 *F.3d* at 170 (stating that "[t]here is no legal precedent for using a name brand manufacturer's statements about its own products as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer has no control."). In this matter, Sandoz chose to replicate the warnings created by Roche and did so at its own risk. While a jury may determine that the warning was adequate, this Court does not find the warning to be adequate as a matter of law and therefore summary judgment as to Count Two is denied.

Count Six

Count Six of Plaintiff's Amended Complaint alleges a Consumer Fraud Act claim against Sandoz. Regarding the Consumer Fraud Act, the New Jersey Supreme Court stated that:

> The Legislature passed the Consumer Fraud Act in 1960 to give consumers relief from fraudulent practices in the marketplace and to deter merchants from employing those practices. *Cox v. Sears Roebuck & Co.,* 138 N.J. 2, 21,647 A.2d 454, 463-64 (1994). Today, the Act makes it unlawful for a person to use "any unconscionable commercial practice, deception, fraud, false pretense, false promise, [or] misrepresentation... in connection with the sale or advertisement of any merchandise ...." *N.J.S.A.* 56:8-2. The Act protects against knowing misrepresentations, omissions of material fact, and violations of administrative regulations, whether or not the merchant acts in bad faith. *N.J.S.A.* 56:8-2; Cox, supra, 138 N.J. at 16-17, 647 A.2d at 463.

[Furst v. Einstein Moomiy, Inc., 182 N.J 1, 11 (2004).]

Plaintiff specifically alleges that Sandoz knew or should have known that mefloquine "was an inherently and unreasonably dangerous and unsafe product and that labeling containing warnings and instructions for use of the drug were inadequate, unsafe, and defective." Amended Complaint at 75. Further it is alleged that Sandoz's statements and/or omissions were undertaken with the intent that Plaintiff would be prescribed the drug. *Id.* at 77. Plaintiff argues that he consumed Mefloquine primarily for personal, family, or household purposes and suffered ascertainable lossed of money due to the "methods, acts, omissions, or practices" used by Sandoz. *Id.* at 78. Plaintiff alleges that Sandoz's actions were in violation of the New Jersey Consumer Fraud Act and Plaintiff suffered ascertainable loss as a direct and proximate result of Defendant.

Sandoz's response to this Count is that only Roche can be held responsible for any misrepresentation or concealment because Roche created the labels used on Mefloquine. This argument is not persuasive to this Court for the reasons previously stated. As noted above, when a generic manufacturer chooses to use the warnings created by another company, it does so at its own risk. Here, Sandoz may have chosen to use the warnings created by Roche without independent investigation and therefore have assumed the risk that they may be flawed or knew they were inadequate and used them anyway. Whether the warnings were flawed and/or constitute a violation of the Consumer Fraud Act, however, is a question to be determined by the fact finder, not as a matter of law. Therefore, summary judgment as to Count Six of Plaintiff's Amended Complaint must be denied.

Count Five

Count Five of Plaintiff's Amended Complaint seeks punitive damages and summary judgment is denied at this time since such damages may or may not be appropriate. This part of the motion can be renewed after discovery ends.

Roche's Motion for Summary Judgment

Roche brings a motion for summary judgment regarding the cross claims asserted by Sandoz. Generally, Roche contends that it has no liability to Plaintiff and, therefore, Sandoz has no right to indemnification or contribution of any kind from Roche. The motion will be addressed by the Count below.

Count Three

Count Three of Sandoz's cross claims alleges that any liability regarding Plaintiff's wrongful misrepresentation or concealment claim is the responsibility of other defendants. As noted *supra,* this claim will be subsumed under either Plaintiff's CFA or PLA claim. As summary judgment regarding this count of Plaintiff's Amended Complaint has already been granted, summary judgment as to Sandoz's cross claim must be granted as well.

Count Four

Count Four of Sandoz cross claim asserts that if any of Plaintiff's allegations of unconscionable business practices are actionable, that the conduct was committed solely or in part by other defendants. Roche asserts in response that it cannot be held liable for the marketing and selling of a product by an independent company and, further, that Sandoz lacks standing to assert a consumer fraud claim in this matter.

The CFA creates a cause of action 'for victims of consumer fraud who have suffered an ascertainable loss." *Smith v. SBC Communs., Inc.,* 178 N.J. 265, 274 (2004) (citing *Weinberg v. Sprint Corp.,* 173 N.J 233, 249 (2002)). Specifically, *N.J.S.A.* 56:8-19 provides that:

> Any person who suffers any ascertainable loss of moneys or property, real or personal, as a result of the use or employment by another person of any method, act, or practice declared unlawful under this act or the act hereby amended and supplemented may bring an action or assert a counterclaim therefor in any court of competent jurisdiction. In any action under this section the court shall, in addition to any other appropriate legal or equitable. relief, award threefold the damages sustained by any person in interest. In all actions under this section, including those brought by the Attorney General, the court shall also award reasonable attorneys' fees, filing fees and reasonable costs of suit.

Further, regarding a fraud "in connection with sale or advertisement of merchandise or real estate as unlawful practice," the statute provides that:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice; provided, however, that nothing herein contained shall apply to the owner or publisher of newspapers, magazines, publications or printed matter wherein such advertisement

> appears, or to the owner or operator of a radio or television station which disseminates such advertisement when the owner, publisher, or operator has no knowledge of the intent, design or purpose of the advertiser.
>
> *[N.J.S.A.* 56:8-2]

Here, Roche has not committed any act that is prohibited by the CFA "in connection with the sale or advertisement of any merchandise." *Id.* The drug ingested by Plaintiff was generic mefloquine produced and marketed by Sandoz. There is no indication to this Court that Roche ever participated in advertising or marketing the mefloquine produced by Sandoz any more than having provided a warning for Lariam® that Sandoz chose to copy rather than petition the FDA to change. Further, having no relation to Sandoz and no beneficial interest in Sandoz selling a generic equivalent of Lariam®, it cannot be logically asserted that Roche intended for its warning label to be relied upon in connection with the purchase of the Sandoz generic equivalent. Also, there is no evidence before this Court that indicates that the New Jersey Legislature intended for prescription drug liability to extend to the name-brand manufacturer when the alleged victim ingested a generic equivalent manufactured and sold by another company. *Roche* cannot be held liable under the CFA. Therefore, summary judgment must be granted with respect to Count Four of Sandoz's Cross Claims.

Count Five

Count Five of Sandoz's cross claims alleges that any liability regarding Plaintiff's failure to warn claim is solely or in significant part the responsibility of other defendants. Sandoz alleges that the warning used on its drug was developed by Roche and that this Court should "recognize that a generic drug manufacturer cannot be held responsible for alleged misrepresentations made to and/or concealment of information from the FDA in the label and warning approval process" that could have only been made by the manufacturer of the name brand drug. Sandoz Opposition Brief at 13. In response, Roche contends that it does not owe a legal duty to a consumer of the generic drug and that Sandoz lacks standing to bring a failure to warn claim.

In a products liability action, "the duty to warn is premised on the notion that a product is defective absent an adequate warning for forseeable users that 'the product can potentially cause injury.' " *Clark v. Safety-Kleen Corp.,* 179 N.J. 318, 336 (2004) (citing *Coffman v. Keene Corp.,* 133 N.J. 581, 593-94, 628 *A.2d* 710 (1993)).

The decision of whether a duty exists is determined by fairness and policy considerations. *See Carvalho v. Toll,* 143 N.J. 565, 573 (1996). In this matter, while it is foreseeable that somewhere down the line, a generic manufacturer could cause harm to a person when producing the equivalent of a name brand drug, but the policy factors weigh against holding the name brand drug manufacturer liable for the actions of a generic manufacturer. More importantly, Sandoz has provided this Court with no evidence to indicate that the PLA was intended to expand liability to the name brand manufacturer in a case such as this. Forcing name brand manufacturers to incur the costs of indemnifying generic manufacturers will only serve to allow the generic manufacturers to "rid[e] on the coattails" of the name brand manufacturer. *See Foster,* 29 *F.3d* at 170. The generic manufacturer would gain all the benefits of selling the drug while passing off all liability. This could only act to stigmatize the ability of companies to develop new and innovative drugs. It also absolves the seller of generic drugs for any responsibility for misinforming the public about its product.

The language of the statute itself appears to indicate the Legislature's intention to restrict liability to specific parties. Specifically, *N.J.S.A.* 2A:58C-2 appears to provide a cause of action only against a manufacturer or seller of a product. The product claimed to be unsafe and provided without adequate warnings is Mefloquine as manufactured and distributed by Sandoz. Roche was neither the manufacturer or seller of Mefloquine.

For these reasons, this Court cannot create a duty on the part of the name brand manufacturer to the consumers of a generic drug and, therefore, an action against Roche under the PLA could not proceed. Therefore, Roche's summary judgment motion against Sandoz's cross claim for failure to warn is granted.

Count One

Sandoz seeks contribution from Roche under Count One. Specifically, Sandoz demands contribution under the Joint Tortfeasors Contribution Act and the Comparative Negligence Act.

1) Comparative Negligence Act

Under the Comparative Negligence Act, a party in a negligence action is permitted to seek contribution based upon the percentage of fault attributable to each party. *N.J.S.A.* 2A: 15-5.2. In the present action, however, there is no negligence action. Without a negligence action, the Comparative Negligence Act does not apply. Therefore, Sandoz cannot seek contribution from Roche under this Act.

2) Joint Tortfeasors Contribution Act

Under the Joint Tortfeasor Contribution Act, a party found liable in tort is permitted to seek contribution from joint tortfeasors. *N.J.S.A.* 2A:53A-2. A joint tortfeasor is defined as "two or more persons jointly or severally liable in tort for the same injury to person or property, whether or not judgment has been recovered against all or some of them."

In this matter, Sandoz has not provided any viable action under which Roche can be found liable in tort. Without having liability, Roche cannot be a joint tortfeasor. Therefore, contribution is not available under the Joint Tortfeasors Contribution Act.

Count Two

Under Count Two, Sandoz seeks indemnification from Roche, In this matter, Sandoz has provided no evidence of an indemnification agreement and has produced no viable claim against Roche from which indemnification may be granted. Therefore, without any viable claim against Roche, indemnification is not available, and summary judgment must be granted.

Roche's Motion for Sanctions

Along with its summary judgment motion, Roche moves for sanctions regarding Sandoz's alleged willful maintenance of frivolous claims. Roche alleges that after receiving Sandoz's cross claims that a demand letter was filed notifying Sandoz of the uniformity of case law holding that a name brand prescription drug manufacturer cannot be held liable for the ingestion of a generic drug manufactured by a different company. In this demand letter, Roche advised Sandoz that sanctions would be sought if the cross claims were not dismissed within 28 days of service of the demand letter.

Rule 1:4-8(3) provides that in filing a paper with the court, the filing attorney certifies that "the factual allegations have evidentiary support or, as to specifically identified allegations, they are either likely to have evidentiary support or they will be withdrawn or corrected if reasonable opportunity for further investigation or discovery indicates insufficient evidentiary support." Further, *N.J.SA.* 2A:15-59.1a(l) provides that;

> A party who prevails in a civil action, either as a plaintiff or defendant, against any other party may be awarded all reasonable litigation costs and reasonable attorney fees, if the judge finds at any time during the proceedings or upon judgment that a complaint, counterclaim, cross-claim or defense of the nonprevailing person was frivolous.

A court must find that one of two elements is satisfied to determine a cross-claim is frivolous. The court must find that either the cross-claim "was commenced, used or continued in bad faith, solely for the purpose of harassment, delay or malicious injury" or that the "nonprevailing party knew, or should have known, that the ... cross-claim ... was without any reasonable basis in law or equity and could not be supported by a good faith argument for an extension, modification or reversal of existing law." *N.J.S.A.* 2A: 15-59.1b(1) and (2).

While Roche alleges that the uniformity of case law prohibits Sandoz from making a good faith argument regarding the cross-claims, this Court cannot agree Of the cases that Rocbe provides in support of its motion only one is a New Jersey case. That case, *Sloan v. Wyeth Inc.,* No. MRS-L-1183-04, slip. op. (Super.Ct.N.J. Oct. 13, 2004), is an unpublished Superior Court decision that is not binding on this Court. While summary judgment was granted on each of Sandoz's cross-claims, it cannot be said that Sandoz was lacking a good faith argument in support of its position. For this reason, Roche's motion for imposition of sanctions is denied.

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CAROL E. HIGBEE, P.J.Cv.

XXXX Order is attached.

Footnotes

1 Of these cases, only one is a reported decision. That decision is *Foster v. America Home Product Corp.,* 29 *F. 3d* 165 (4th Cr. 1994).

2 The Counts included in Sandoz's motion for partial summary judgment are Product Liability: Failure to Warn (Count Two) Wrongful Misrepresentation/Concealment (Count Thee), Punitive Damages (Count Five), Consumer Fraud (Count Six).